

#ROC-0641-01
APPEAL TO FINAL REVIEW PG. 2

~~THESE~~ WHEN I INQUIRE ABOUT TESTS, POSSIBLY ALLERGIC IN NATURE OR IRON COUNT (WHICH IS INCONSISTENT) OR THE POSSIBILITY OF CANCER (BECAUSE OF ALPHA ~~FETA~~ PROTEIN COUNTS), THE RISE ONCE AGAIN IN MY ALT'S + AST'S. THIS IS ALL VERY SCARY TO ME, THE NOT KNOWING WHATS GOING ON WITH MY BODY. I'VE BEEN GETTING VERY EXHAUSTED AGAIN LATELY, I HAVE ABDOMINAL PAIN ALOT AND I'M NOT GETTING ANSWERS. THIS FEAR TURNS INTO ANGER WHEN I'M TOLD EVERYTHING THAT CAN BE DONE IS BEING DONE WHEN ITS SO OBVIOUS THAT I FEEL NOTHING IS BEING DONE, AND IN THE LAST LINE TO SAY MY SITUATION IS BEING MONITORED FOR CHANGES. AT WHAT POINT DOES SOMETHING GET DONE?

I BEG YOU TO RECONSIDER THE PREVIOUS REPLIES I'VE GOTTEN AND ORDER A BIOPSY, PEGOLATED INTERFERON AND MORE TESTING TO GET TO THE BOTTOM OF THE INCESSANT ITCHING I ENDURE EVERYDAY. THANK YOU.



WILLIAM M. CLARK

AY-5585

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF CORRECTIONS
2520 LISBURN ROAD, P.O. BOX 598
CAMP HILL, PA 17001-0598

THE SECRETARY'S OFFICE OF
INMATE GRIEVANCES AND APPEALS

October 10, 2001

William Clark, AY-5585
SCI-Rockview

Re: DC-ADM 804 – Final Review
Grievance No. ROC-0641-01

Dear Mr. Clark:

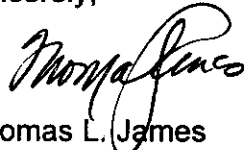
This is to acknowledge receipt of your appeal to final review of the above numbered grievance.

In accordance with the provisions of DC-ADM 804, effective January 1, 2001, I have reviewed the entire record of this grievance; including your initial grievance, the grievance officer's response, your appeal from initial review and the superintendent's response. I have also carefully reviewed the issues you raise to final review.

Upon completion of this review, it is the decision of this office to uphold the responses provided by staff at the institutional level. It appears that the medical personnel, including Dr. Symons, are acutely aware of your medical condition and despite your request from specific treatment protocols, monitoring of your conditions is ongoing. I see no legitimacy in your grievance based on the care being administered.

The responses provided at the institutional level are appropriate and in accordance with Department of Corrections policies and procedures. Accordingly, your appeal to final review must be denied.

Sincerely,



Thomas L. James
Chief Grievance Coordinator

TLJ/rh

cc: Superintendent Meyers
Grievance Office
Central File

Hepatitis C infections strain prison system

By Karen Roebuck
TRIBUNE REVIEW

Almost one in five Pennsylvania prison inmates has hepatitis C, creating public health and economic problems as taxpayers increasingly pick up the tab for expensive treatments.

"The sheer numbers — that's problem No. 1," said Dr. Frederick Maue, medical director of the state Department of Corrections.

More than 19 percent of Pennsylvania prisoners — 7,476 of them — are infected. Treating and monitoring one inmate with the liver-wasting disease costs as much as \$20,000 a year.

In state prisons systems around the nation, as few as 12 percent and as high as 40 percent of inmates are infected with hepatitis C, said Dr. Cindy Weinbaum, an epidemiologist with the U.S. Centers for Disease Control and Prevention who works with the federal Bureau of Prisons. Only 1.8 percent of the general population, or 3.9 million people, has contracted the disease.

Because most inmates will be released into society, health officials worry about the spread of the highly contagious, usually chronic and potentially fatal virus. Hepatitis C is the biggest reason for liver transplants.

Sufferers often feel exhausted but do not show any serious symptoms for 20 or more years. They become ill with life-threatening conditions, such as liver disease, liver cancer, kidney failure, autoimmune diseases, diabetes or lymphoma. With millions believed to have contracted the disease in the 1970s and 1980s through blood transfusions and intravenous drug use, an onslaught of health problems related to hepatitis C is expected in the coming decade.

Already, it's estimated that complications of hepatitis C cost the nation \$1.5 billion a year in direct and indirect costs, said Dr. Thomas Shaw-Stiffel, a specialist with the Center for Liver Diseases at UPMC Health System.

Officials are not sure why the infection rate is so much higher

among inmates but speculate that their pre-incarceration lifestyles put them at higher risk.

Most susceptible are those who share needles to inject drugs, get tattoos in unsanitary conditions or had blood transfusions before 1992, when more sensitive screening was developed. The risk of contracting the disease through sexual contact increases with multiple partners. Once a person is infected, using alcohol, cocaine or illegal intravenous drugs often speeds the disease's progression.

Between 75 percent and 80 percent of hepatitis C infections become chronic; the rest go away without treatment.

Until threatened a few years ago with lawsuits from inmates, the state Department of Corrections did not give prisoners medication that could cure hepatitis C, treating only the symptoms or serious, often life-threatening complications. The state did screen every inmate for the disease.

Hepatitis C was second only to cardiac disease as the leading cause of death among Pennsylvania's inmates in 2000 and 2001, said Maue, the prisons' medical director. Through last month, 19 inmates had died from the disease this year.

Those infected tend to suffer "difficult deaths," requiring frequent or prolonged treatment and hospitalization, Maue said. Hospitalization during the end stage of liver disease costs the state about \$110,000.

Pennsylvania will spend about \$9 million this budget year to treat about 730 inmates, Maue said. That figure represents less than 10 percent of those infected.

Maue said Pennsylvania prison officials face heavy criticism from corrections officials in other states for providing any treatment because many people can safely delay treatment.

"But we're seeing our inmates die right now, and it's costing large amounts of money to have inmates go in and out of the hospital," he said.

PLEASE SEE HEPATITIS/A12

Doctors have differing opinions on when to treat the typically slow-progressing disease.

The standard treatment now is a combination of drugs: pegylated interferon, an injection, and ribavirin, a pill.

The Department of Corrections spends \$11,594 per inmate for the full 48-week treatment, which most prisoners need.

Those infected with hepatitis C also are vaccinated against hepatitis A and B, which are less serious and caused by different viruses.

Hepatitis C patients are not more likely to contract those diseases. But because the other viruses also attack the liver and cause similar symptoms, they would hit hepatitis C patients harder, experts said.

Besides being expensive, the drugs come with many side effects and, until recent improvements, were ineffective for most patients. The treatment can cause severe flu-like symptoms. Because complications from the disease take so long to develop, waiting to treat some patients is a reasonable option, experts agree.

Even so, UPMC's Shaw-Stiffel said, "The trend now, in general across the country, is to recommend treatment because of the high success rate."

The two-drug treatment cures about 55 percent of those with hepatitis C, he said, up from 40 percent in 1998 and 10 percent in 1991. The success rate varies among the six types of the virus.

For patients who don't respond to treatment, doctors have been able to do little more than treat the symptoms and complications.

Prisoner advocates accuse Pennsylvania prison officials of looking for too many reasons to exclude infected inmates from treatment. Still, they acknowledge the department is doing far better than most states since it began offering treatment in 2000.

A former inmate, Robert Lassen, provided the impetus for change. Lassen said he contracted hepatitis C from a blood transfusion in 1977. The disease was detected when he entered prison in 1991 after convictions for assault and intimidation of a witness.

Lassen said he learned of his condition five years later while being treated for other health problems. He said prison doctors told him not to worry about the problems. But when he became seriously ill a year later, he started his own investigation, both of the dis-

or inmates' health problems.

He collected affidavits from more than 40 other inmates who said they were not told they had hepatitis C. Some of the infected inmates had been released on parole and found out they had tested positive only after they landed in prison again, Lassen said.

Lassen and others filed lawsuits demanding treatment, and the prisoner-advocacy group Pennsylvania Institutional Law Project intervened to negotiate a solution.

Anxious to avoid costly legal battles, the state Department of Corrections formed a task force in 1999 to reduce the state's liability and to treat patients, said Maue, who was hired as prison medical director after serving on the task force. The department began treating inmates the next year.

A cost-benefit analysis convinced legislators that not treating inmates would cost more in the long run, Maue said. The state ultimately will save \$3 to \$4 for each dollar it spends now to treat hepatitis C, he said.

Hepatitis C accounts for half of the liver transplants in the United States. An unidentified Pennsylvania inmate with hepatitis C is a candidate for a liver transplant, pending acceptance by the transplant team at an unidentified university. Maue estimated the procedure would cost the state \$250,000 to \$500,000.

A sustained treatment program would spare most patients and the prison system that pain and expense, advocates say.

Lassen, 46, who now lives in the Detroit suburb of Roseville, was not treated for hepatitis C while in prison. But as a result of his tenacity, hundreds of other inmates have been.

He was reassured by medical tests and treatment after being paroled in 2000. But the treatment did not help him, and he wonders whether it would have been more effective had he received it earlier.

Lassen dropped his lawsuit over treatment but won a \$6,501 judgment against the state because prison officials had punished him for pursuing the issue.

Now, he sees his fight with Pennsylvania prison officials as his legacy.

"At least my life had some meaning," Lassen said. "I changed the world; I saved some lives."

Karen Roebuck can be reached at kroebuck@tribweb.com or 412-320-7939.

EXH. D

HEPATITIS C QUESTIONNAIRE

As indicated in my previous memo, you are being considered as a plaintiff in a class action law suit being brought on the hepatitis C epidemic within Rockview and the DOC. To assist the attorney in making decisions relating to this law suit, and to help him decide who might actually be named in the suit, he will need some information about you and your medical situation. This questionnaire will be treated as confidential, and with the exception of myself and the attorney, it will not be seen by any other plaintiff, or anyone else. The questions are similar to some of the questions the attorney asked me during our consultation. So while some of the questions may not appear to be relevant, the attorney has his reasons for requesting this type of information. Please be forthcoming and straightforward in your answers. Fill out the questionnaire to the best of your ability, and use additional paper if necessary.

1. Name & Number:

WILLIAM M. CLARK #AY-5585

2. Nature of crime(s) and length of sentence. Include the date of sentencing if known, and dates of minimum and maximum sentence.

see #2 - notes

3. Where were you processed when you first came into the state system? For example, were you processed in the Classification or Diagnostic unit at SCI-Pittsburgh, at SCI-Camp Hill, etc.?

SCI GRATERFORD

4. Everyone is given a physical examination, including a blood test, when they enter the prison system. Sometimes the blood tests are routine, and sometimes they are looking for something specific based on your medical history or because of your answers to certain questions. For example, they may have told you they were testing for HIV-AIDS, diabetes, anemia, etc., or they may have said nothing. After they took your blood, did they call you back and tell you anything or give you a diagnosis? For example, if they did not give you an exact diagnosis, did they indicate that you might have a problem such as low or high blood sugar, that your liver enzyme levels were elevated, that your blood pressure was high, etc.? Explain.

#4 - NOTES

5. To the best of your recollection, what month and year did you arrive at Rockview?

see notes #5

6. To the best of your recollection, when were you first told that you had the hepatitis C virus ("HCV")? -- were you told before or after you arrived at Rockview? Explain.

OCT. 1999 - AFTER - (SEE NOTES)

7. After you were told you had HCV, did they counsel you in any way? For example, did they explain how the disease is spread; did they tell you anything about what is harmful to your liver; did they say anything about medications you should or should not take; did they say anything about foods or diets, etc.? Explain.

see #7 - notes

8. After you were told you had HCV, did you ask about treatment? If so, to the best of your recollection, what were you told?

SEE #14 & NOTES.

9. After you were told you had HCV, was a liver biopsy ever discussed by you or your doctor? If a liver biopsy was discussed, to the best of your recollection, give details and any relevant dates.

IN OCT. '99 I WAS TOLD BY MARY JO THAT UNLESS MY
CONDITION GOT ALOT WORSE I WOULD NOT HAVE THE BIOPSY

DONE.

NOTE: SEE JOURNAL

10. You are aware from information provided by me that some inmates are now receiving interferon and ribavirin to treat their HCV. Did any medical personnel tell you about treatment now available, or did you only hear this from me or other inmates?

I WAS TOLD BY THE MEDICAL PERSONNEL THAT THERE IS
A TREATMENT, BUT THAT BECAUSE MY COUNT WAS ONLY
"SLIGHTLY ELEVATED" AND THAT "THE LEVELS DON'T CHANGE THAT
(P.A. FINN) MUCH", THAT BEFORE I COULD ACCEPT OR REJECT TREATMENT I
WOULD HAVE TO WAIT UNTIL MAY, 2000 BEFORE A DECISION WAS MADE

11. Before you were told of your HCV, were you receiving regular or sporadic blood tests? For example, did they regularly or sporadically take your blood and not tell you why? If they told you why, what was the reason they gave you? Explain.

NO.

12. After you were told of your HCV, did they regularly begin testing your enzyme ("ALT") levels? — if yes, what was or is the frequency of these tests. Explain. List all ALT levels, if known.

NO - ALT LEVEL (OCT. 99) - 66 -

(P.A. FINN)
TOLD AT CONSULTATION IN DEC '99 THAT BECAUSE I WAS ONLY SLIGHTLY ELEVATED & THAT LEVELS DON'T CHANGE THAT MUCH THAT I WOULD NOT BE TESTED AGAIN FOR 6 MOS. (APRIL, 2000)

NOTE: SEE JOURNAL

13. Have you seen a specialist in State College about your HCV? If yes, give as much information as you can about this consultation, and detail any recommendations he might have made.

NO,

14. Are you currently being treated for your HCV? If yes, provide all relevant information. For example, how long after you were told you had HCV did treatment begin; when was the approximate date you started receiving treatment; are you getting both interferon (a shot) and ribavirin (a pill); have they tested your viral load after you began treatment, and if so, has it gone down, and so on. . . . Provide any information you think might be important — use additional pages if necessary.

(CAS OF JAN. '2000)
NO - NO TEST FOR VIRAL LOAD, I DID ASK DR. SYMONS BECAUSE ANOTHER INMATE SAID THAT WAS IMPORTANT. HE BASICALLY SAID BECAUSE OF THE ONLY SLIGHTLY ELEVATED ENZYMES & THE VIRAL LOAD WASN'T A BIG DEAL.

JUNE '2000 - NOT SURE WHAT PROMPTED CHANGE IN OPINION AS TO STARTING HCV TREATMENT (STARTED SEEING DR. EGGLER APPROX. APRIL, 2000), BUT WAS TOLD I SHOULD START MEDS. BEFORE PLATELET COUNT GOT ANY LOWER. PLT → (129,000). STARTED MEDS (HCV) - 9/15/00; NO TO VIRAL LOAD COUNT SINCE (COMB. TRTMT.) STARTING.

14. Have you requested treatment since treatment began being provided at Rockview yet were turned down? For example, if you were turned down for treatment, was it by a doctor here, or did a doctor here make a treatment recommendation to Wexford and they turned you down? Be specific if you can. Also, were you given any reason(s) for being denied treatment. Again, be specific.

(OCT. 99)

ASKED MARY JO WHY THEY WOULDN'T START TREATMENTS ON SOMEONE WHILE THEY STILL HAVE LOW ~~ENZ~~ ENZYME LEVELS, WOULD IT HAVE BETTER RESULTS THEN FOR SOMEBODY WHO'S LEVELS ARE HIGH OR WAIT FOR IT TO GET WORSE? TOLD THAT I'M SAFE WHEN ^{LEVELS} I'M AT & THEN TOLD ABOUT HOW IT WORKS, AND HOW IT USUALLY RE-OCCURS AFTER 2 YRS.

15. Are you currently suffering any symptoms that you are aware of that you think might be related to your HCV, or that a doctor told you were related to your HCV? If yes, what are those symptoms and how are they affecting your life and daily activities?

I'M TIRED ALL THE TIME, MAY GO ONE WEEK WHERE THAT DOESN'T OCCUR & THEN IT HITS ME AGAIN. GET MORE HEADACHES ~~RE~~ LATELY.

16. Do you know how you "might" have contracted HCV? For example, did you receive a blood transfusion prior to 1992; were you an intravenous drug user; did you engage in unprotected sex with someone who might have been infected with HCV; did you ever have hepatitis A or B; and/or did you get a tattoo or have any body piercing? Add to this any estimation as to how long you might have had HCV.

I HAVE BEEN TOLD JUST LATELY (OCT. 99) THAT I HAD HEP A NEVER KNEW IT. I HAD USED IV DRUGS FOR ALOT OF YEARS & HAD HAD UNSAFE SEX & GOTTEN ^(AFTER 1990) TATTOOS. I HAVE NO IDEA HOW I MAY HAVE HAD HCV. (AT LEAST SINCE 1992)

17. Has any doctor told you that you may have suffered damage to your liver from having HCV? For example, has it been suggested or have you been diagnosed as having cirrhosis, tumors, cancer, fibrosis, scarring, and/or bridging?

MARY JO EXPLAINED TO ME THAT ANYBODY WITH HCV MAY HAVE SOME DEGREE OF LIVER DAMAGE.

AS OF 11/5/2000, (EXCEPT FOR CHARTS GIVING ^{CHRONIC 90'S} ~~OF~~ ^{OF} POPULATION INFECTED W/HCV) HAVE NEVER BEEN TOLD BY A DOCTOR HERE HOW THE DISEASE PROGRESSES OR AT WHAT LEVEL OF DISEASE I AM CURRENTLY AT. (SEE JOURNAL)

18. Have you had or has any doctor recommended that you receive a liver biopsy, a liver scan, an ultrasound, or any other form of diagnostic testing? If you had any of these procedures, explain what was found in each case. If you have not had any of these procedures, has a doctor recommended you receive any procedure but said procedure was denied by Wexford? Explain in detail if possible, and give any approximate dates.

NO.

* UNTIL SOMEWHERE BET. APRIL & JUNE 2000, WHEN I WAS GIVEN
AN ULTRASOUND (RESULTS - DIFFUSELY ENLARGED LIVER - _____ CM.
ENLARGED SPLEEN, NO TUMORS SEEN)

19. Have you ever filed a Section 1983 law suit? If yes, is it pending today; was it dismissed as frivolous; was it settled; did you go to trial; did you withdraw the suit? Explain and provide the complete caption if known.

NO.

20. If I did not do it for you, did you file a grievance relating to your HCV? ~~did~~ did you appeal to the Superintendent? ~~did~~ did you appeal to final review?

YES TO 1ST. (LOGGERT HAD FILE 12/10)

* HAVE GONE THRU THOSE APPEALS SINCE THEN

21. Will you sign a release to have the attorney obtain your medical records, and will you sign a contingency fee agreement so that the attorney can be paid for his services? (A "yes" or "no" answer covers both questions).

YES.

22. Provide any other information you believe might be relevant.

(SEE JOURNAL)

NOTES (FROM HEP. C QUESTIONNAIRE) (1)

(2) ? - 5-15 yrs. NOV. 29, 1984 - NOV. 29, 1999 - ^{6 YRS.} STREET TIME ^{NEW MAX. 0}
 TAKEN THIS LAST TIME OUT FOR 3RD DEGREE MISDEMEANOR (PROVIDING ALCOHOL TO A MINOR) GOT ^{MAX. SENT.} 6-12 MONTHS FROM COUNTY → DID THIS TIME BET. GRATERFORD & HERE AND THEN STARTED 9 MONTH HIT W/ REVIEW - SAW BOARD IN JAN. '97 AND HA DONE 2 MORE 1 YR HITS SINCE THEN.

(4) 1985 - GRATERFORD - WAS NOT CALLED DOWN TO MED. DEPT. FOR ANYTHING RELATED.

1989 - RELEASED TO CCC

1992 - RETURNED TO D.O.C. - GRATERFORD - 6 MONTH HIT FOR NOT COMPLETING ^{DRUG} PROG
 (FROM TEST I SAW IN OCT. '99 - BLOOD RESULTS SHOW MY ENZYME ^(HIGH) ~~WAS~~ OUT OF NORMAL RANGE - I WAS NEVER TOLD OF ANY PROBLEM
 (DID SEE ^(HIGH) ON 2 CATEGORIES OF RESULTS)
 RELEASED FROM D.O.C. - 9/92
 (GRAT) ~~(FROM MED.)~~

1995 - RETURNED TO D.O.C. - PASS. OF COCAINE - 1 YR PROB. - BEAT PAROLE BOARD ON 120 RULE - TESTS ~~WAS~~ MARY JO HAD (OCT '99)
 DID NOT SEE THOSE RESULTS BUT SHE TOLD ME MY LEVELS WERE IN THE NORMAL RANGE.

RELEASED FROM D.O.C. - 4/96

NOV/1996 - RETURN TO GRATERFORD - PROV. ALCOHOL TO MINOR - ALSO TOLD BY MARY JO IN OCT '99 THAT LEVELS WERE IN NORMAL RANGE, (AT THAT TIME)
 OCT/1999 - ASKED FOR HIV & HCV - HEP. C TEST AND WAS GIVEN HIV TEST. (NE - WAS TOLD BY MARY JO WHEN CALLED IN FOR HIV RESULTS, THAT ENZYMES WERE HIGH & THAT THEY WERE GOING TO DO THE HCV TEST TEST WAS TAKEN & I WAS CALLED IN AND TOLD ~~THAT~~ THAT I HAVE HEP. C - ALSO TOLD THAT I HAD HAD HEP. A & HEP. B AT SOME POINT & THAT I HAD FOUGHT THEM OFF. AT THIS TIME ~~IS~~ WHEN I WAS SHOWN RESULTS OF PRIOR TESTS TAKEN AT PRIOR INTAKES TO D.O.C. (SEE ABOVE) WAS TOLD DR. SUMERS ~~WAS~~ DR. SUMERS ~~WAS~~ DR. SUMERS

62

SOMETIME IN THE FUTURE, ABOUT HEP. C - WASN'T CALLED OVER - SAW HIM APPROX 2-3 WKS LATER FOR UNRELATED MEDICAL PROBLEM (PSORIASIS) AND AT THAT TIME HE NOTICED RESULTS OF BLOOD TESTS.

⑤ ARRIVED GRATERFORD 8/85 - NOT SURE WHEN I CAME TO ROCKVIEW - EITHER
LATE '85 OR EARLY '86.

⑥ I HOPE I'VE EXPLAINED WHAT YOU NEED IN QUESTION 4.

7) FIRST SHE SHOWED ME A CHART OF %'S OF PEOPLE CHRONIC + NON CHRONIC, GAVE ME A COPY. SHE SAID ~~HEP C~~ WAS SPREAD THRU THE BLOOD-SITTING NEEDLES, ETC. MARY JO SAID ALCOHOL ~~COULD~~ WOULD BE DANGEROUS TO ME. SHE TOLD ME ABOUT INTERFERON + RIBAVIRIN + THAT I PROBABLY WOULDN'T RECEIVE THEM BECAUSE MY LEVELS ARE ONLY SLIGHTLY ELEVATED. THE DOCTOR TRIED TO RUN THE SAME STUFF I INFORMED HIM ^(DR. STANIS) MARY JO SHOWED ME THE CHART. HE GAVE ME VITAMINS WHEN I ASKED IF THERE IS ANYTHING I COULD DO, DIET, ETC. ON WED. 12/1/99 I WAS TOLD TO REPORT TO THE P.A. ^(FINN) SHE SAID I WAS THERE FOR MY HEP. C. IT WAS BASICALLY THE SAME AS BEFORE AT FIRST-WANTED TO SHOW ME THE %CHART, TOLD ME ABOUT THE MEDS AVAILABLE, THAT I WASN'T HERE TO ACCEPT OR REJECT MEDS AVAILABLE. WHEN I ASKED FOR ANOTHER TEST, SHE SAID THAT LEVELS DON'T CHANGE THAT MUCH + THAT MY NEXT TEST WOULD BE IN APRIL 2000 (6 MONTHS 1ST TEST) AT THAT TIME THEY WOULD CHECK MY IRON + VIRAL ~~LOAD~~ ². ALSO SAID AT THIS TIME THAT IT WOULD PROBABLY BE MAY OF 2000 BEFORE THERE WOULD BE A DECISION ~~ON~~ WHO WOULD BE ELIGIBLE FOR TREATMENT. SHE ALSO TOLD ME ABOUT ALCOHOL + DRUGS

(3)

- ⑦ CONT. - FLU LIKE SYMPTOMS, DEPRESSION, NOT FATHERING A CHILD FOR 6 MOS. AFTER TREATMENT ENDS (POSSIBLE BIRTH DEFECTS), NOW IF I DID GET TREATMENTS AND STOPPED BECAUSE OF SIDE EFFECTS, I WOULD NOT BE ALLOWED TO RE-START TREATMENT JUST BECAUSE EFFECTS HAD WORN OFF AND I NOW FELT I SHOULD GET THE TREATMENT. NOT INFORMED OF ANY SPECIAL NEEDS, DIET OR MEDS UNTIL MAY-JUNE, 2000 (LIMITED INFORMATION)
- ⑧ YES & WAS TOLD BY MARY ~~TO~~ ^(FINN) AND THE P.A. ^(SEE NOTES #7) THE ABOVE. ALSO WHEN I SAW THAT 45% RATE OF PEOPLE WHO GET BETTER THAN MEDS. ALSO TOLD THAT WITHIN 2 YRS. CONDITION RE-OCCURS.

⑫ NO - (see notes)

EXT. E

No. _____

CONSULTATION RECORD

Part A: To be completed by referring institution:		Type of Consult: <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> On-Site <input checked="" type="checkbox"/> Off-Site
Referred to: Dr Haight	Referred by: (physician name) Symons MD	Appt. Date: MAR 7/00
Specialty: GI		Appt. Time:
Drug Sensitivity: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (Specify)		
Copies of lab and X-ray results attached? Yes No If yes, specify: MAK 7/00 ULS		
Reason for Referral: Liver Bx		
History of Injury/Problem:		Date of Onset:
<p>Hepatitis C - Dx 10/99 - but probably of long duration. Tx with Interferon + Ribavirin - VL 678,000 → 267,000 @ 6 months. Interferon + Ribavirin stopped at that point due to Urologic failure after dialysis 5 p.t. then Treat for Fournier's 7800 c phlebomy → Fournier's abs 19</p>		
Treatment to Date/Current Medications and Significant Medication History: α Fetoprotein 71 → 21 → 42, ULS neg for mass in liver 7/00 platelet low at 119,000		
<p>Imp - At this point liver Bx is PDX - Psoriasis needed to determine degree of Fibrosis or if cirrhosis is present - this will help us determine how aggressive to be in Tx</p>		
Signature of Referring Physician		Date
SP 16/0 SYMONS MD		4/10/01
Approval <input checked="" type="checkbox"/> Disapproval <input type="checkbox"/> Medical Director Signature		Date
Transmittal Date: 7/11/01		Transmitted By: jam
Approval Date:		Approved By:
Part B: To be completed by consulting Physician and returned with officer to the institution:		
Diagnosis and Recommendations:		
<p>Alternate plan 7/11/01</p> <p>appeal denied 7/17/01</p>		
Signature of Consulting Physician		Date

Consultation Record
Commonwealth of Pennsylvania
Department of Corrections
DC-441

Inmate Name: **Clark, William**
Inmate Number: **AY 5585**
DOB: **9-11-54**
Institution: **Rockview**

**FP
R**

A supplement to:

Family Practice Recertification®

A peer-reviewed clinical journal for primary care physicians

June
Vol. 22, No. 6

HEPATITIS C VIRUS

*Establishing the Standards of
Diagnosis and Treatment*

Offers 2 Hours of Category 1 CME Credit

Sponsored by Johns Hopkins
University School of Medicine

Supported by an unrestricted
educational grant from Schering

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of HCV in the general population and in special high-risk groups. Individuals in the following categories have a higher prevalence of HCV infection: those with a history of religious scarification; intravenous drug use or intranasal cocaine use; exposure to needles, sharp instruments, and blood or blood products; tattooing; immune globulin injections; treatment for schistosomiasis; sexually transmitted disease, having had more than 50 sexual partners; male homosexual sexual behavior; or infection with the human immunodeficiency virus (HIV) or the hepatitis B virus (HBV); and those who have been incarcerated or are veterans.¹⁰ Patients with a risk factor should undergo testing for HCV, HBV, and HIV.

Screening, evaluating, testing, counseling, and educating patients build awareness of HCV and could also identify patients who might benefit from treatment. Knowledge of test results enables the physician (1) to inform the patient accurately about having an infectious disease; (2) to define which patients should be screened for liver cancer and evaluated for systemic or extrahepatic sequelae of HCV; (3) to determine who should undergo biopsy and subsequent treatment; and (4) to provide advice about the need for barrier methods during sexual contact.

Standard testing of HCV-antibody reactive patients

PCR testing is the most sensitive method for the detection of HCV infection and is also used to measure the viral levels in serum or blood. PCR should be considered the test of choice in patients with normal levels of liver enzymes and no risk factors for HCV.⁷ As many as 15% of patients are HCV seronegative after acute infection. Serum HCV PCR testing is not required to document disease in a patient with elevated liver enzymes and a history of high-risk behavior, because in those patients, the occurrence of disease is highly probable. Quantitative PCR testing is used in that patient group to manage therapy and to document response to treatment. PCR testing is also important in dialysis patients,¹¹ in whom antibody testing may have a false-negative rate that approaches 50%.¹²

Testing for genotype before the initiation of treatment is also commonly used to determine which patients may benefit most from treatment. The HCV genotype is used to predict the chance of "cure" or sustained response, which is defined by

Table 1

Evaluation of chronically elevated ALT

- Stage 1
 - HCV antibody
 - Alcohol history
 - HBsAg
 - Medication/OTC/herbal history
 - Assessment for fatty liver
 - Weight, lipid profile, glucose
 - Iron saturation
- Stage 2
 - Autoimmune workup
 - ANA, ASMA, AMA, SLA, ANCA
 - Alpha-1 antitrypsin level and phenotype
 - Wilson's disease
 - Ultrasonography (mass, obstruction, stones)
 - Liver biopsy
 - ERCP (if alkaline phosphatase/GGT > ALT)
- Stage 3

<ul style="list-style-type: none"> - Hepatic congestion <ul style="list-style-type: none"> • echocardiography or cardiac catheterization - Budd Chiari syndrome <ul style="list-style-type: none"> • Doppler - Hepatitis X - Glycogen storage disease <ul style="list-style-type: none"> • PAS stain of liver - Sarcoid <ul style="list-style-type: none"> • ACE - Thyroid disease - Congestive hepatic fibrosis/Caroli's disease - Amyloid - Cystic fibrosis 	<ul style="list-style-type: none"> - Advanced autoimmune tests <ul style="list-style-type: none"> • SLA, LSMP, F Actin - HBV PCR - HCV PCR - Systemic autoimmune disease <ul style="list-style-type: none"> • Pericholangitis • Sprue • Lupus • Psoriasis - Parasite <ul style="list-style-type: none"> • Schistosomiasis • Echinococcosis
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ACE = angiotensin converting enzyme; AMA = antimitochondrial antibody; ALT = alanine transaminase; ANA = antinuclear antibody; ANCE = antineutrophil cytoplasmic antibody; ASMA = anti-smooth muscle antibody; ERCP = endoscopic retrograde cholangiopancreatography; GGT = gamma-glutamyl transferase; HBsAg = hepatitis B surface antigen; LSMP = liver specific membrane protein; OTC = over the counter; PAS = periodic acid-Schiff; SLE = systemic lupus erythematosus.

PCR results that show persistent HCV negativity after treatment. Prediction of the duration of response is important in counseling patients and in determining which patients should undergo treatment. Combination therapy with interferon and ribavirin should be used for 12 months in patients with genotype 1 and for 6 months in patients with a genotype other than 1.¹³ Many patients are now so sophisticated that they may request HCV genotype testing when they first receive the diagnosis of HCV infection. Most studies¹⁴ have shown that genotype-like serum levels of virus do not correlate with the clinical prognosis (i.e., the risk of progression to cir-

rhosis), the risk of liver cancer, serum levels of liver enzymes, or symptoms.¹⁴

Management of patients with abnormal and normal liver enzymes

Aspartate aminotransferase (AST) and ALT are liver enzymes that are used in amino acid metabolism. These liver enzymes should be discussed only in the context of liver inflammation; no direct relation exists between the level of elevation of an enzyme and liver histologic factors or liver dysfunction. Conversely, liver function (synthetic) tests are evaluations of clearance. They are used to determine levels of albumin, bilirubin, international normalized ratio or prothrombin time, ammonia, and cholesterol and are useful in determining the severity of liver disease in patients with cirrhosis or severe acute liver injury. All patients with suspected or proven viral hepatitis should undergo such testing. If the liver function (synthetic) test results are abnormal, referral to a tertiary-care organization for a liver transplant evaluation should be considered.

The definition of "normal liver enzymes" should be addressed. Most clinical laboratories define a range of AST or ALT levels in international units per liter (IU/L) by testing a small number of individuals and establishing a range within 2 standard deviations. It is important to realize that the prevalence of obesity in 40% of the population in the United States probably explains the presence of fat and fatty liver as causes of elevated liver enzymes in as many as 20% of patients in a primary care doctor's practice. Alcohol abuse or dependence is found in 15% of the population, and medications that are potentially hepatotoxic as well as viral infections, iron overload, and various illnesses are other common causes of chronically elevated liver enzymes. Information on the normal and abnormal ranges of liver enzymes and how those ranges pertain to body mass index has now been published.¹⁵ Those data and internal reviews at local hospitals have resulted in the use of ~ 31 IU/L as the upper limit of normal for ALT and AST levels by a number of laboratories in the United

→ States. Any level of liver enzyme elevation above that normal range should lead to the evaluation of the patient and to strong consideration of having the patient undergo liver biopsy to facilitate diagnosis or staging of the severity of liver disease.

In patients with abnormal liver enzyme levels,

the fluctuations in serum levels of ALT and AST appear to have no direct relationship to histologic factors in those who have not been treated with antiviral medications¹⁶ or to serum HCV RNA levels or patient outcome.¹⁷ Liver biopsy should be seriously considered in patients with indirect signs of progressive liver disease, such as a progressive decrease in liver function (synthetic) test values, a low white blood cell count or platelet count.¹⁸

The natural history of chronic liver disease in patients with normal liver enzyme levels should be further defined, although a significant amount of data are now available.¹⁹ It appears that patients who have chronic liver disease and normal liver enzyme levels, the risk of the development of cirrhosis is significantly lower than 7%. Sequential liver enzyme level testing is recommended for these patients; liver biopsy can then be performed if serum levels of liver enzymes are elevated. Liver biopsy results can be used to direct treatment if marked fibrosis is observed (stage 3 or 4) or within the context of clinical trials to evaluate patients with normal liver enzyme levels.¹⁹

Special situations

Testing sexual partners of patients with hepatitis C infection and children born to mothers with chronic HCV disease is recommended, although the risk of vertical or sexual transmission appears to be less than 3%-5% in most settings. Severe hepatitis is more likely to develop in patients who have chronic liver disease as a result of viral hepatitis. It has been suggested that patients infected with HCV undergo vaccination against hepatitis A virus (HAV) and HBV, that all patients with chronic HBV undergo vaccination against HAV. There are no recommendations for the vaccination of those patients to prevent influenza, pneumococcal infection or infection by bacteria of the genus *Haemophilus*, although that topic merits consideration.

HCV has now been associated with a variety of extrahepatic diseases (including cryoglobulinemia) that may lead to multiorgan involvement and death.²⁰⁻³⁰ Patients with immune complex disease that is attributable to HCV infection should be considered candidates for interferon therapy. All patients with chronic HCV infection should be examined for renal damage by assessment of serum creatinine levels and albuminuria levels as well as by physical examination to detect

ropathy and vasculitis.

Coinfection with HCV and HBV increases the risk of cirrhosis and decompensated liver disease.^{32,33} For the treatment of such patients, clinicians may wish to consider using the same doses of interferon that are used to initiate treatment in patients with HBV infection only (5 million units or 10 million units, 3 times weekly for 16 weeks, and then reduce to 3 million units, 3 times weekly to complete 6-12 months of therapy, depending on the genotype of the HCV virus).

HIV coinfection with HCV often (but not always) indicates a poor outcome, such as end-stage liver disease.^{34,35} Patients with HIV and HCV coinfection may be candidates for interferon therapy if aggressive liver disease is documented by liver biopsy and if the patient's life expectancy (based on CD4 cell counts and history of opportunistic infections) is long.^{22,24,36} Also important in evaluating such patients is their compliance with HIV regimens, their HIV RNA levels, and the presence or absence of medication-induced liver disease. Patients with HCV may be at increased risk of liver damage as a result of highly active antiretroviral treatment or antituberculosis drug therapy.

Liver cancer occurs in 20% of patients with HCV infection and cirrhosis and rarely occurs in patients with less advanced disease. Therefore, screening for liver cancer by means of alpha-fetoprotein level evaluation and ultrasonographic study is advised yearly or twice yearly in patients with cirrhosis detected by liver biopsy or with clinical evidence of decompensated liver disease.

Use of liver biopsy for patient management

Physicians can take one of two approaches to the management of patients with chronic hepatitis C: (1) treating all such patients without performing a liver biopsy or (2) customizing treatment recommendations based on the histologic results of liver biopsy.

The biopsy score, when combined with the probable time of infection with HCV, provides an index by which physicians can assess and predict the rate of liver disease progression. In counseling patients with HCV infection, it is important to use known estimates of prognosis that are based on the results of liver biopsy to help define each patient's outcome with respect to progressive liver disease.³⁷ A minority of patients have mild liver disease that progresses to more severe liver disease over time. Increased inflammation, piecemeal

necrosis (interface hepatitis), and fibrosis may be associated with a risk of progression to cirrhosis and liver failure or cancer. The prevention of progressive fibrosis³⁸ and cirrhosis that can occur after interferon therapy³⁹ is probably the most important therapeutic endpoint that has been documented by means of sequential liver biopsies. In some patients, liver histologic factors may revert to normal after 3 to 5 years. Liver biopsy is also useful in differentiating autoimmune liver disease from chronic HCV infection, in ruling out biliary obstruction, in determining the amount of fat in the liver, and in identifying an excess level of iron.

Prospective and retrospective studies indicate that the prevalence of progression to cirrhosis is probably less than 7% in the absence of interface hepatitis. If interface hepatitis is present without fibrosis, the long-term risk of cirrhosis is 20%-30%. If extraportal fibrosis, bridging inflammation, or necrosis is observed, the chance of progression is greater than 70%. The risks associated with undergoing a liver biopsy are quite low: The possibility of experiencing serious pain is less than 5%; that of bleeding, less than 1:10,000; and that of death, 1:10,000. The cost of treatment is estimated to range from ~ \$10,000-\$20,000, and the cost of undergoing liver biopsy is \$1,500. The possible need for liver biopsy should be discussed with all patients, and the decision to perform a liver biopsy should be supported by the treating physician. More than 85% of practicing gastroenterologists perform a liver biopsy before offering treatment for HCV, according to recent surveys.

Evaluation and management of patients with acute HCV infection

HCV infection results in chronic disease in more than 85% of people with acute infection. An intuitive approach to therapy, such as that used in the treatment of HIV infection, supports the use of early intervention. Current recommendations from the Centers for Disease Control and Prevention indicate that patients who have sustained potential exposure to HCV infection should undergo liver tests and antibody testing at 6 months after exposure. Other clinicians use a more aggressive approach and recommend testing for HCV RNA by PCR at relatively short intervals (for example, 2 weeks and 4 weeks or 1 month and 3 months after exposure). If the serum test results are positive for HCV RNA, immediate treatment is recommended.

HEPATITIS C

Table 1

→ Assessment of HCV before, during, and after therapy⁴Before therapy

- Perform a liver biopsy to confirm the diagnosis of HCV, assess the grade and stage of disease, and rule out other diagnoses. When a liver biopsy is contraindicated (such as in patients with clotting disorders), combination therapy can be given without a pretreatment liver biopsy.
- Measure serum HCV RNA by PCR to document that viremia is present.
- Test for the HCV genotype to help determine the duration of therapy.
- Measure the blood count and the aminotransferase level to establish a baseline for these values.
- Counsel the patient about the relative risks and benefits of treatment. Side effects should be thoroughly discussed.

During therapy

- Measure the blood count and the aminotransferase level at weeks 1, 2, and 4 and at 4- to 8-week intervals thereafter.
- Adjust the dose of ribavirin downward (by 200 mg at each adjustment) if significant anemia occurs (hemoglobin < 10 g/dL or hematocrit < 30%) and stop ribavirin if severe anemia occurs (hemoglobin < 8.5 g/dL or hematocrit < 26%).
- Measure HCV RNA by PCR at 24 weeks of therapy. If HCV RNA is still present, stop therapy. If the HCV RNA test result is negative and patient exhibited genotype 1 (1a or 1b), continue therapy for another 24 weeks.
- Reinforce the need to practice strict birth control during therapy and for 6 months thereafter.
- Measure thyroid-stimulating hormone levels every 3 to 6 months during therapy.
- When therapy has been terminated, test HCV RNA by PCR to assess whether there is an end-of-treatment response.

After therapy

- Measure the aminotransferase level every 2 months for 6 months.
- Six months after the termination of therapy, test for HCV RNA by PCR. If the HCV RNA test result is still negative, the chance for a long-term "cure" is excellent; relapses have rarely been reported after that point.

Adapted from National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Chronic Hepatitis C: Current Disease Management (<http://www.niddk.nih.gov>).

of IFN- α . Thus, an understanding the goals of antiviral therapy for each patient is important in identifying which patients should be treated and in determining appropriate treatment strategies.

Therapy for chronic HCV infection

In the United States, IFN- α is approved by FDA for the treatment of chronic hepatitis C infection alone (monotherapy) or in combination with ribavirin. IFNs are a family of naturally occurring proteins produced and secreted by cells in response to viral infection. Multiple subtypes of IFN- α , including IFN- α 2b, interferon alfa-2a (IFN- α 2a), and alfacon-1 (consensus IFN), all of which are administered by subcutaneous injection three times weekly, are produced by recombinant techniques. Currently, "combination therapy" refers to treatment with IFN- α 2b administered in conjunction with ribavirin, an orally available synthetic guanosine nucleoside analogue. Combination therapy consistently yields higher rates of sustained virologic response than does IFN monotherapy, and has become the standard of care for the treatment of chronic HCV infection.

• **IFN monotherapy** Even before the discovery of the hepatitis C virus, IFN- α was shown to decrease serum ALT levels in patients with non-A, non-B hepatitis. In 1986, Hoofnagle et al published promising results from an uncontrolled pilot study of 10 patients treated with IFN- α . In 1998, more than 10 years after the completion of that study, those findings assumed greater significance with the subsequent report that 5 of the 10 patients exhibited no evidence of HCV RNA in serum or liver tissue and demonstrated major regression of hepatic fibrosis suggestive of eradication of chronic HCV infection.³

Subsequent randomized controlled trials established the effectiveness and limitations of several types of IFN- α administered three times weekly for treatment of chronic HCV infection. When considered together, those clinical trials demonstrated that ~ 50% of patients receiving IFN- α achieved a normalization of serum ALT level by the end of 6 months of treatment; unfortunately, nearly half experienced biochemical relapse after therapy was terminated. Meta-analysis of 32 IFN- α clinical trials suggested that longer duration of IFN monotherapy (12-18 months) was associated with a decreased incidence of relapse and improved, sustained biochemical response rates. As a result of those and other data, in 1997, the National Institutes of Health (NIH) Consensus Development Panel supported the use of IFN- α administered three times weekly for 12 months. However, these treatment recommendations

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NATIONAL
PSORIASIS
FOUNDATION

NPF

EXH. F,

Bulletin

VOL. 28, NO. 1

Jan/Feb 1997

Don't Curse the Darkness:

Dealing with the stress of a chronic condition

The old saying "What you see is what you get" is not really true for psoriasis. While it affects the outside of the body in a painful, visible way, it can have a significant effect on the inside — on self-esteem, self-image and even identity. Its assault on the psyche can be overwhelming.

The good news is that researchers are studying the factors that determine the psychosocial impacts of psoriasis and other skin disorders, and they are educating dermatologists about how to treat them.

Psychodermatology

"The intensity of the impact of skin disease on an individual person is extremely variable: some are devastated by a few blemishes, whereas others with chronic visible disease shrug it off and go briskly about their business," said Iona Ginsburg, M.D., of the Columbia-Presbyterian Medical Center in New York City.

Published in a collection of scholarly articles about "psychodermatology" in the July 1996 *Dermatology Clinics*, Dr. Ginsburg's piece, "The Psychosocial Impact of Skin Disease," discusses the many variables that determine how a person deals with a skin disorder such as psoriasis.

According to Dr. Ginsburg, the first of these variables is the "natural history and implications" of a particular condition. By this, she means that a person will react differently to a skin disease based on whether it is genetic or acquired. The timing of onset is also important. A person will react differently to a disease that is present from birth than one that shows up in a difficult period such as adolescence.

Chronic skin conditions such as psoriasis are likely to have a greater impact than self-limited skin ailments. The manifestations of the skin condition, i.e., redness, open sores, tenderness, burning and itching, can influence a person's ability to cope. Likewise, the location of lesions can affect a person's work life, social life and even sex life.

Another variable is the "treatability" of the condition. A person who has to use greasy, smelly topicals, take time off work to get light therapy, or take systemic drugs with potential side effects is bound to be affected by the disorder's intrusion on daily life.

Characteristics of the patient

A person's age, sex, general physical health and personality type also have a role in the skin disorder. According to Dr. Ginsburg "because personality type presents a filter that tends to alter experience in characteristic ways, one can observe responses to skin disorders as distinctive according to personality."

A person's self-esteem and body image before the onset of the skin disorder are indicative of how the person will cope.

"Basically, an individual's self-image relates to early developmental experiences, as how the young child was perceived, accepted, and taken care of within the family," she said.

Environment has a role

The support of coworkers, friends, family and close loved ones is critical. "If people have devoted friends and family, they probably will weather the storm of emotions and practical problems generated by a severe or chronic skin disease much better than if this network is weak or nonexistent," said Dr. Ginsburg. People with psoriasis who are gainfully employed felt "less guilt, shame and sensitivity to others' opinions and attitudes as well as anticipating rejection to a lesser degree," she reported. Nonetheless, experiences of rejection by others can be devastating.

Disability

The skin is an organ that protects the body against environmental injury. It also regulates heat and sensory perception, and it "displays" the human being inside. When the skin

Continued on page 2

This article was reprinted from the *Bulletin*, Jan/ Feb, Vol. 28, No. 1, membership newsletter of the National Psoriasis Foundation®.

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BULLETIN

NATIONAL PSORIASIS FOUNDATION

The Role of Stress in Psoriasis

If you have psoriasis, you may have been told that psoriasis is a result of nervousness or stress. You don't hear this from medical experts, but from well-meaning people who have heard and remembered this long-discounted myth.

While stress and emotion aren't the cause of psoriasis, that doesn't mean they have no role in psoriasis. Some people with psoriasis have been able to identify the stressful situation that preceded a flaring of the lesions. Others find that stress interferes with the commitment to treatment.

There is evidence that management of stress during treatment might bring better results. In some cases, self-diagnosis of stress could effect the course of the disease. The focus of several articles in this issue is to suggest stress-reduction techniques that have been found helpful. We would be interested to hear whether you have experienced an improvement of psoriasis through stress management or relaxation techniques.

Studies Investigate Stigma, Insight and Stress in Psoriasis

Recent studies published in the Journal of the American Academy of Dermatology have concerned themselves with psoriasis and stress, and with the extent that people with psoriasis feel stigmatized (discredited or set apart) by their psoriasis. Studies were carried out in the U.S., England and Canada.

The Stigma of Psoriasis

Feelings of stigmatization have important implications, not only for the quality of life of those with psoriasis but for the clinical management of patients. Despair may cause afflicted patients to abandon treatment. As their skin worsens, patients feel still more the stigma of psoriasis.

That's the conclusion of Iona H. Ginsburg, M.D. and Bruce G. Link, Ph.D of Columbia University, New York, who con-

Studies reveal a variety of findings when feelings, stigma, stress and psoriasis are investigated.

ducted the study. Dr. Ginsburg is a psychiatrist who works with the Department of Dermatology at the Columbia-Presbyterian Medical Center and Dr. Link is an epidemiologist with the School of Public Health. Their study appeared in the January 1989 Journal.

Continued on page 3

NPF Pharmacy Is Open For Business

MEDIC Pharmacy, Inc. is the mail order agent for NPF. Service is in place and orders are being taken by telephone. To order by phone, call toll free 1-800-562-9206 and then NPF referred you. You will need to have your Visa, Master or Discover card number and expiration date at hand. Mail orders will be sent to MEDIC Pharmacy, Inc., 1016 Clay St., Portland, OR 97201. Whether ordering by telephone or by mail, mention that you are an NPF member or have been referred by NPF.

MEDIC Pharmacy, Inc. has been an industry leader in mail order service and Fugy, Registered Pharmacist, has been with them since its beginning in 1962. His son, Chris, is also a Registered Pharmacist and works at MEDIC.

To kick-off the service, each member of NPF will receive an order form and a pharmacy catalog in October. Subsequently, those who request it or who order will receive the quarterly catalog update. A person may request a pharmacy catalog at any time.

The pharmacy service is intended to serve the needs of psoriasis patients by providing quantities of psoriasis prescriptions.

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Studies Investigate Stigma, Insight and Stress in Psoriasis

Continued from page 1

One hundred adult patients ranging from 20 to 70 years were studied. Fifty-one were hospitalized for treatment of their psoriasis. Eighteen were clinic outpatients, and 31 were private outpatients. Seventy-five percent had moderate to severe disease. Eleven of the hospitalized patients refused to participate for reasons that suggested anxiety. One said, "There are questions there I don't want to think about."

The researchers drew up questionnaires. Answers provided by patients pointed out six factors underlying the stigma experience: anticipation of rejection, feelings of being flawed, sensitivity to the opinions of others, guilt and shame, positive attitudes and secretiveness.

The study disclosed that many people do feel stigmatized, but others do not. "Why some people with psoriasis shrink away from social interaction whereas others handle strangers, coworkers, friends, and family with aplomb has something to do with such issues as how old they were when psoriasis started and whether or not they are working (employed)," the authors concluded, but other factors are also involved. Perhaps the employed person feels less vulnerable, or perhaps some jobless people in the study can't work because of the physical or emotional disability of psoriasis, the authors speculate.

One factor that emerged was "positive attitudes." This surprised the researchers. People reflected optimism about their children should psoriasis develop; felt that people close to them aren't put off by the psoriasis; or did not feel that people with psoriasis are "treated like lepers." Researchers did not know if this might represent "whistling in the dark", the denial or suppression of bad experiences, or a transformation of negativity through religious feeling or other means.

They also found that people who get psoriasis in adulthood are less likely to anticipate rejection, to feel sensitive to the opinions of others or to feel guilt or shame. They are not as secretive about psoriasis. The more years a person has psoriasis, the less guilt, shame and secretiveness the person will feel.

"Clearly these findings attest to the extreme vulnerability of those who experience an early onset of psoriasis," the study said. Younger people, more sensitive to other people's opinions and having a heartfelt expectation of rejection, must come to terms with psoriasis as they achieve maturity. Perhaps, suggest the authors, any person whose psoriasis started at a young age might benefit from group therapy or short-term individual therapy that focuses on their experience with psoriasis.

Other interesting aspects of the study:

A person who experiences high despair may also have positive feelings; contradictory feelings are held at the same time.

Patients with family members who have psoriasis are less secretive, those who have a child with psoriasis are more secretive (don't want to talk about psoriasis.)

Women are more likely to experience psoriasis-related despair.

Ninety-three people in the study population experienced itching.

Bleeding is related to feelings of being flawed and strongly related to despair, sensitivity, guilt and shame.

Insight and Empathy

A second study in the January 1989 *Journal* was titled "Stress and psoriasis: the importance of insight and empathy in prognosis." R.H. Seville, M.D., Lancaster, England, concludes that the prognosis improves "when patients understand the stress flare phenomenon and gain insight into the nature of any emotional trauma they have suppressed." Dr. Seville said the interval between the stress and the flaring of psoriasis is about a month. "There must be empathy

on the part of the physician" and a "mosphere that helps a patient look and pinpoint the triggering event, although "to have gained insight is of the patient's own doing."

Dr. Seville also said that psoriasis should be cleared quickly and completely at first onset. When a year lapses between onset of psoriasis to seeking medical attention, only 24% were free of psoriasis a year's follow up. When the time was less than a year, 44% remained free.

Stressful factors and severity

Stressful factors can contribute to the severity of psoriasis symptoms; according to a Canadian study of five patients published in the *Journal* in 1987. The results suggest that patients suffering from psoriasis could benefit from psychological intervention aimed at reducing stress according to the authors.

However, patients need to be evaluated on an individual basis before they learn a psychological technique to help control the severity of their psoriasis symptoms because the relationship between psoriasis and stress did not hold for all five subjects. "The contribution of psychosocial factors varies from one disease to another, from one person to another, and from one episode of illness to another in the same person," according to the study. The design of the study matched the responses of the five patients equal to a study with 100 independent observations. Louise Gaston, Ph.D., Department of Psychology, University of Montreal coordinated the study.

Stress/Worsening Link Absent

Psychologists and dermatologists from the United Kingdom studied 16 patients who significantly worsened psoriasis by means of a mail questionnaire. They asked them to identify recent life events, and then rate them on a scale of severity. The researchers also assessed whether the effect of stress would be moderated by the degree of social support a person has.

The study did not find that psoriasis was significantly worsened by "life events" and that social support exerted only a very small influence. They said that the findings did not rule out the existence of a subgroup for whom stress is a crucial precipitating factor. The study was published in *Clinical and Experimental Dermatology* in 1985.

Hepatitis C treatment a costly prison issue

State's care of inmates
criticized on both sides

By Karen Roebuck
TRIBUNE-REVIEW

Almost one in five Pennsylvania prison inmates has hepatitis C, creating public health and economic problems as taxpayers pick up the tab for increasingly expensive treatments.

"The sheer numbers — that's problem No. 1," said Dr. Frederick Maue, medical director of the state Department of Corrections.

More than 19 percent of Pennsylvania prisoners — 7,476 of them — are infected. Treating and monitor-

ing one inmate with the liver-wasting disease costs as much as \$20,000 a year.

In state prison systems around the nation, as few as 12 percent and as high as 40 percent of inmates are infected with hepatitis C, said Dr. Cindy Weinbaum, an epidemiologist with the U.S. Centers for Disease Control and Prevention who works with the federal Bureau of Prisons. Only 1.8 percent of the general population, or 3.9 million people, has contracted the disease.

Because most inmates will be released into society, health officials worry about the spread of the highly contagious, usually chronic and potentially fatal virus. Hepatitis C is the biggest reason for liver transplants.

Sufferers often feel exhausted but do not show any serious symptoms for 20 or more years. They become ill with life-threatening conditions, such as liver disease, liver cancer, kidney failure, autoimmune diseases, diabetes or lymphoma. With millions believed to have contracted the disease in the 1970s and 1980s through blood transfusions and intravenous drug use, an onslaught of health problems related to hepatitis C is expected in the coming decade.

Officials are not sure why the infection rate is so much higher among inmates but speculate that their pre-incarceration lifestyles put them at higher risk.

Most susceptible are those who share needles to inject drugs, get tattoos in unsanitary conditions or had blood transfusions before 1992, when more sensitive screening was developed. The risk of contracting the disease through sexual contact increases with multiple partners. Once a person is infected, using alcohol, cocaine or illegal intravenous drugs often speeds the disease's progression.

Between 75 percent and 80 percent of hepatitis C infections become chronic; the rest go away without treatment.

Until threatened a few years ago with lawsuits from inmates, the Pennsylvania Department of Corrections did not give prisoners medication that could cure hepatitis C, treating only the symptoms or serious, often life-threatening, complications. The state did screen every inmate for the disease.

Hepatitis C was second only to cardiac disease as the leading cause of death among Pennsylvania's inmates in 2000 and 2001, said Maue, the prisons' medical director. Through last month, 19 inmates had died from the disease this year.

Those infected tend to suffer "difficult deaths," requiring frequent or prolonged treatment and hospitalization, Maue said. Hospitalization during the end stage of liver disease costs the state about \$110,000.

Pennsylvania will spend about \$9 million this budget year to treat about 730 inmates, Maue said. That figure represents less than 10 percent of those infected.

Maue said Pennsylvania prison officials face heavy criticism from corrections officials in other states for providing any treatment because many people can safely delay treatment.

"But we're seeing our inmates die right now, and it's costing large amounts of money to have inmates go in and out of the hospital," he said.

Doctors have differing opinions on when to treat the typically slow-progressing disease.

The standard treatment is a combination of drugs: pegylated interferon, an injection, and ribavirin, a pill. The Department of Corrections spends \$11,594 per inmate for the full 48-week treatment, which most prisoners need. Those infected with hepatitis C also are vaccinated against hepatitis A and B, which are less serious and caused by different viruses.

Hepatitis C patients are not more likely to contract those diseases. But because the other viruses also attack the liver and cause similar symptoms, they would hit hepatitis C patients harder, experts said.

Besides being expensive, the drugs come with many side effects and, until recent improvements, were ineffective for most patients. The treatment can cause severe flu-like symptoms. Because complications from the disease take so long

to develop, waiting to treat some patients is a reasonable option, experts agree.

Even so, "The trend now, in general across the country, is to recommend treatment because of the high success rate," said Dr. Thomas Shaw-Stiffel, a specialist with the Center for Liver Diseases at UPMC

Health System.

The two-drug treatment cures about 55 percent of those with hepatitis C, he said, up from 40 percent in 1998 and 10 percent in 1991. The success rate varies among the six types of the virus.

For patients who don't respond to treatment, doctors have been

EXT

SEE 8
51

Fast facts about hepatitis C					
About the disease					
Signs and symptoms					
<ul style="list-style-type: none"> ■ Fatigue ■ Pain in the right side of the abdomen ■ Loss of appetite ■ Nausea ■ No signs or symptoms in about 80 percent of cases 					
Long-term effects					
<ul style="list-style-type: none"> ■ Chronic infection: 75-85 percent of infected people ■ Chronic liver disease: 70 percent of chronically infected people ■ Deaths from chronic liver disease: Less than 3 percent ■ Leading cause of liver transplants 					
Transmission					
<ul style="list-style-type: none"> ■ Occurs when blood or body fluids from an infected person enter the body of a person who is not infected. ■ Hepatitis C is spread through sharing intravenous needles, through needle sticks, the job or by an infected mother to her baby during birth. ■ Those at risk for hepatitis C infection might also be at risk for infection with hepatitis B or HIV. 					
Hepatitis C in prisons					
Prison population	Infected with hepatitis C	Receiving treatment	Completed treatment	Refused treatment	Under evaluation
Dec '00 36,810	4,646 (12.6%)	346	Not available	Not available	1,274
June '02 39,136	7,476 (19.1%)	365	525	2,072	3,540

Source: Pennsylvania Department of Corrections; Centers for Disease Control and Prevention

Tribune-Review

Cost of treatment



The most common course of hepatitis C drug therapy, using pegylated interferon and ribavirin (above) for 48 weeks: **\$11,594**

Depending on the type of hepatitis C, some patients need to be on the medicine for six months: **\$6,280**

Hospitalization for cirrhosis: **\$30,980**

Cost of liver transplant:
At least \$250,000

Cost of hospitalization for end-stage liver disease, resulting in death:
\$110,000

Source: Pennsylvania Department of Corrections

Tribune-Review

able to do little more than treat the symptoms and complications.

Prisoner advocates accuse Pennsylvania prison officials of looking for too many reasons to exclude infected inmates from treatment. Still, they acknowledge the department is doing far better than most states since it began offering treatment in 2000.

A former inmate, Robert Lassen, provided the impetus for change. Lassen said he contracted hepatitis C from a blood transfusion in 1977. The disease was detected when he entered prison in 1991 after convictions for assault and intimidation of a witness.

Lassen said he learned of his condition five years later while being treated for other health problems. He said prison doctors told him not to worry about the prob-

lems. But when he became seriously ill a year later, he started his own investigation, both of the disease and what he sees as a cover-up of inmates' health problems.

He collected affidavits from more than 40 other inmates who said they were not told they had hepatitis C. Some of the infected inmates had been released on parole and found out they had tested positive only after they landed in prison again, Lassen said.

Lassen and others filed lawsuits demanding treatment, and the prisoner-advocacy group Pennsylvania Institutional Law Project intervened to negotiate a solution.

Anxious to avoid costly legal battles, the state Department of Corrections formed a task force in 1999 to reduce the state's liability and to treat patients, said Maue, who was hired as prison medical director after serving on the task force. The department began treating inmates the next year.

A cost-benefit analysis convinced legislators that not treating inmates would cost more in the long run, Maue said. The state ultimately will save \$3 to \$4 for each dollar it spends now to treat hepatitis C, he said.

Hepatitis C accounts for half of the liver transplants in the United States. An unidentified Pennsylvania inmate with hepatitis C is a candidate for a liver transplant, pending acceptance by the transplant team at an unidentified university. Maue estimated the procedure would cost the state \$250,000 to \$500,000.

A sustained treatment program would spare most patients and the prison system that pain and expense, advocates say.

Lassen, 46, who now lives in Roseville, Mich., was not treated for hepatitis C while in prison. But as a result of his tenacity, hundreds of other inmates have been.

He was reassured by medical tests and treatment after being paroled in 2000. But the treatment did not help him, and he wonders whether it would have been more effective had he received it earlier.

Lassen dropped his lawsuit over treatment but won a \$6,501 judgment against the state because prison officials had punished him for pursuing the issue. Now, he sees his fight with Pennsylvania prison officials as his legacy.

"At least my life had some meaning," Lassen said. "I changed the world; I saved some lives."

William M. Clark
#AY-5585

EXH. H

CHRONOLOGY (1)

- OCT, 1999 - AFTER 2 MONTHS OF FEELING LISTLESS AND GETTING TIRED REAL EASILY, I PUT IN A REQUEST TO THE MEDICAL DEPT. REQUESTING ~~AND~~ HIV AND HEPATITIS C TESTING. LATER IN THE MONTH I WAS CALLED TO THE MEDICAL DEPT. TO SEE MARY JO. TOLD I WAS NEGATIVE FOR HIV BUT THAT I HAD HEPATITIS C (PROBABLE) AND THAT I WOULD GET MORE TESTING. SHORTLY AFTERWARD I ~~WAS~~ AGAIN SAW MARY JO, WHO INFERRED ^{ME} THAT I'D HAD HEP. A+B AND FOUGHT THEM OFF, BUT THAT I DID HAVE HEP. C (CHRONIC) BECAUSE BY BLOOD WORK DONE IN 1992 MY ENZYMES WERE HIGH THEN. I WAS SHOCKED AND ANGRY AT THIS NEWS AS I WAS NEVER TOLD. WHEN I ASKED WHY THEY WOULDN'T HAVE TOLD ME THIS, MARY JO SAID THERE REALLY WASN'T ANYTHING THEY COULD DO ANYWAY. INQUIRED ABOUT TREATMENTS, TOLD WOULD TREAT (INTERFERON + RIBAVIRIN) WHILE ENZYME LEVELS ARE ONLY MODERATELY ABOVE THE NORM. WHEN I STATED WOULDN'T IT BE BETTER TO TREAT EARLY, TOLD I WAS SAFE WHERE LEVELS WERE. ALT AT THIS CONSULT WAS 66. TOLD I WOULD SEE DR. SYMONS ~~IN~~ ~~DECEMBER~~ SOMETIME IN THE FUTURE. ~~THE~~ ~~ARE~~ ~~THE~~
- ~~NOV.~~ 1999 - SAW DR. SYMONS ON UNRELATED MATTER (PSORIASIS). AT THAT TIME HE NOTICED RESULTS OF BLOOD TESTS. HE GAVE ME SOME INFO ON HEP. C. (90% OF ~~CHRONIC~~ ^{PEOPLE} ~~ARE~~ INFECTED, ~~HOW~~ MANY CHRONIC, GAVE ME PAMPHLET ON HOW CONTRACTED, ETC.) ASKED IF THERE WAS ANYTHING I COULD DO (DIET, ETC.) GIVEN VITAMINS
- 12/1/99 - TOLD TO REPORT TO P.A. FINN IN MEDICAL DEPT. - TOLD IT WAS A HEP. C AWARENESS CONSULT, SHE STARTED TO GIVE ME THE PAMPHLETS, TOLD HER MARY JO HAD RUN ALL THAT BY ME. SHE FELT MY STOMACH FOR PAIN (I ~~HAD~~ NONE). SHE TOLD ME ABOUT THE TREATMENTS AVAILABLE, THAT I WASN'T THERE TO ACCEPT OR REJECT

(2)

12/1/99⁹ - MEDICATIONS AVAILABLE. I ASKED FOR ^{A FOLLOW-UP} BLOOD TEST, SHE SAID THAT LEVELS DON'T CHANGE THAT MUCH AND THAT MY NEXT TEST WOULD BE IN APRIL 2000 (6 MCS. FROM 1ST TEST) AND THAT THEY WOULD CHECK MY IRON AND VIRAL LOAD. ALSO TOLD IT WOULD PROBABLY BE MAY OF 2000 BEFORE THERE WOULD BE A DECISION ON WHO WOULD BE ELIGIBLE FOR TREATMENT. ALSO TOLD ME NEGATIVE SIDE EFFECTS - DEPRESSION, FLU LIKE SYMPTOMS ETC. ALSO TOLD IF I STOPPED TREATMENTS BECAUSE OF SIDE EFFECTS WOULD NOT BE ALLOWED TO RE-START. (WROTE GRIEVANCES, ENCLOSED)

JAN' 2000 - SAW DR. SYMONS, ASKED ABOUT A VIRAL LOAD BECAUSE SOMEONE HAD TOLD ME ITS IMPORTANT - HE BASICALLY TOLD ME THE VIRAL LOAD WASN'T A BIG DEAL BECAUSE OF ONLY SLIGHTLY ELEVATED ENZYMES.

APRIL 2000 - STARTED SEEING DR. EGGLER - TOLD MY ENZYMES WERE ONLY SLIGHTLY ELEVATED, NO NEED TO START TREATMENTS, HAD ME CONVINCED I'D BE BETTER OFF WAITING UNTIL NEXT YEAR WHEN THE NEW DRUG WOULD BE APPROVED. (PEGOLATED?)

JUNE-JULY 2000 - WASN'T BEING TOLD MUCH BUT STARTED GETTING CALLED DOWN TO MED. DEPT A LOT (POSSIBLY HAD TO DO WITH NEW PROTOCOL) SONOGRAPHY ORDERED - RESULTS - DIFFUSELY ENLARGED LIVER, ENLARGED SPLEEN, NO TUMORS SEEN.

AUGUST 2000 - DR. EGGLER INFORMED ME I SHOULD GO AHEAD AND START TREATMENTS BEFORE MY PLATELETS DROPPED ANY MORE. SHE SAID NEW TREATMENT WOULD BE APPROVED IN JAN. 01 BUT BECAUSE OF "POLITICS" WE WOULD NOT BE RECEIVING IT ANY TIME SOON. TOLD MY IRON COUNT IN FEB? WAS HIGH AND THAT I SHOULD CUT BACK ON RED MEATS + NOT TO USE VITAMINS SOLD HERE (IRON CONTENT) ALT-73, AST-69, HGB-16.7, WBC-7.2 PLATELETS-129,000. CONSULT FOR 8/31/00 SET UP. (SEE JOURNALS) TOLD I WOULD HAVE VIRAL LOAD DONE. CONTINUED → TRANSCRIBED

AUG. 6, 2001

A Health Danger From a Needle Becomes a Scourge Behind Bars



Edward Keating/The New York Times

Edward McKenna, a New York inmate with hepatitis C, says he is being denied life-saving treatment.

Prison Authorities Seek a Response to High Hepatitis C Rates

By DAVID ROHDE

Prison officials say that nearly 10,000 inmates in New York and thousands more across the country are infected with hepatitis C, an insidious liver infection that is difficult to treat, has no definite cure and, over many years, kills 5 percent of those who contract it.

Prison and public health officials are wrestling with how to respond to the surprisingly high rates of infection, trying to figure out how to contain its spread, and how and when to provide expensive treatment that in most cases does not work. Some states are treating hundreds of prisoners infected with hepatitis C, while others are treating none.

And beyond concerns about how to manage the problem inside the prisons — guards, for instance, fear being infected through contact with inmates' blood — health officials worry that prisoners may spread hepatitis C through intravenous drug use when they are released.

A study to be submitted to Congress this fall estimates that 18 percent of state prisoners nationwide — or about 360,000 inmates — are infected with the virus.

"There are still legitimate scientific questions about who the treatment will ultimately benefit," said Dr. Robert Greifinger, a senior fellow for the Centers for Disease Control and Prevention in Atlanta, who led a study for the Justice Department. "On the other hand, the infection rates are very, very high. I just don't think it's very clear yet how to manage the problem."

Dr. Greifinger based his study on projections from several state studies. Many states are just starting to survey inmates for the infection.

In New York, a first-ever survey recently estimated that 14 percent of the state's 69,000 prisoners have hepatitis C. In Pennsylvania, about 6,200 of the state's 36,500 prisoners are infected. In Connecticut, the rate is believed to be 15 percent of 17,500 inmates. New Jersey has not broadly tested for the virus.

The Northeast is hardly alone in grappling with this health problem. In California, officials estimate that 33 percent of the state's 161,000 pris-

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EXH
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2ND PAGE

Health Danger From Needle Becomes Scourge in Prisons

PG. 2

Continued From Page A1

oners have hepatitis C. In Texas, 28 percent of the state's 157,000 prisoners are believed to be infected.

"It's simmering and brewing and if it boils over, the medical costs will be catastrophic," said Dr. Frederick R. Maue, chief of clinical services for Pennsylvania's Department of Corrections, which is actively treating infected inmates. "There will be liver transplants, multiple hospitalizations to treat liver failures, and increased numbers of deaths."

Doctors say the problem is not that large numbers of prisoners are contracting hepatitis C while incarcerated; most were infected through intravenous drug use and shared needles years ago. It is that the infection's breadth and power are only now becoming clear.

New screening tests developed in the early 1990's have found that far more people are infected than was ever expected, although many people who contract it suffer few ill effects. But some people who were infected as long ago as the 1960's are dying today, underscoring the fact that the disease can prove fatal over the course of 20 to 30 years.

Hepatitis C, which causes liver disease in 20 percent of its victims, slowly kills 5 percent over two to three decades. Because of such statistics, doctors describe the infection as more of a potential medical time bomb than an immediate public health threat. Roughly 2.7 million people are infected with the virus in the United States, nearly three times the number who test positive for H.I.V., the virus that causes AIDS. Eight thousand people die of illnesses related to hepatitis C each year.

Hepatitis C is a blood-borne virus that can linger for years without causing symptoms, and is the leading cause of liver transplants in the United States. Aside from intravenous drugs users, hundreds of thousands of other people are believed to have contracted the disease from blood transfusions before the early 1990's, when effective screening tests were developed.

Vaccines exist for two other hepatitis viruses. Hepatitis A, which can be transmitted by food, food handlers and water, rarely kills those it infects. Hepatitis B is a sexually transmitted disease that kills 5,000 people a year.

The infection rate among the general population for hepatitis C is far lower — 1.8 percent — than in pris-

ing me I'm going to die and that's the way it is," said Mr. McKenna, who expects to live only two more years at best. "They won't treat me."

Mr. McKenna, a slight man with an eyeglass case and ballpoint pen tucked in his shirt pocket, looks like an accountant. But he has a criminal history dating back to 1966. In 1990, he shot his younger brother during a backyard argument in Brooklyn.

The murder, which Mr. McKenna called an accident, led to a prison sentence of 10 to 20 years.

In July 1999, Mr. McKenna was diagnosed with hepatitis C, something he believes he contracted while injecting drugs when he was an Army private stationed in Thailand in the early 1960's.

Mr. McKenna said he asked for treatment in September 1999, but a prison doctor told him he was not eligible because he had an appearance coming up before the parole board within a year. New York, like other states, follows guidelines from the National Institutes of Health that say only people who will be available for a full year of intensive care should be treated. Otherwise, the treatment is ineffective.

But when Mr. McKenna appeared before the parole board a year later, he, like 80 percent of violent offenders in the state, was denied parole and given two more years in prison.

Jack Beck, a lawyer for the Legal Aid Society who is advising Mr. McKenna, said that prison doctors used parole board appearances as a pretext for denying them the costly treatment. In a medical document provided by prison officials, a doctor wrote that Mr. McKenna did not qualify for treatment because his earliest anticipated release date was his parole board appearance.

But Mr. Beck said the chances of a violent offender like Mr. McKenna being released by the parole board were slim. The expiration of an inmate's sentence, not the next parole board appearance, should be used when deciding treatment, he said.

"It's definitely a rationing protocol," he said, referring to New York's rules for deciding who to treat. "It's very expensive and they clearly don't want to treat people."

Dr. Lester N. Wright, chief medical officer for the New York Department of Correctional Services, said the state's procedures met national standards, and that prison doctors did not use inmates' parole board appearances to deny treatment. "I usually look at the conditional release date," he said, referring to the expiration of a prisoner's sentence.

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CONT. PG. 3 COL. 2

Fears of a potential medical time bomb in 10 to 20 years.

ons. Doctors believe the infections are concentrated among inmates because of their high rate of intravenous drug use before being jailed. The disease may also be gradually spreading in prisons. Studies show that 3 percent to 21 percent of inmates say they engage in intravenous drug use while incarcerated. Forty-four percent of those who reported drug use said they shared needles.

The infection's death toll is rising and is expected to grow steadily over the next 10 to 20 years. In New York prisons last year, where \$70 million was spent to treat roughly 1,400 inmates with AIDS, eight inmates died of that disease. Nine died of illnesses related to hepatitis C.

The question of how best to treat the infection has provoked debate in medical circles. For some people, no treatment is required. But for those who show evidence of developing liver disease, it is widely accepted that treatment is advisable.

Expensive new drug treatments, costing \$10,000 to \$20,000 per patient annually, show signs of curbing the infection. But they are effective in only 15 to 45 percent of cases, have serious side effects and sometimes even make the patient sicker.

States are responding differently to the problem. Some are waiting for better treatments before developing a formal plan of action, while others are actively treating their inmates. In New Jersey and Maryland, for instance, no prisoners are currently receiving treatment. But in Pennsylvania, 417 prisoners are being treated. New York is currently treating 95 prisoners at a cost of about \$6 million a year.

Inmates in various states, including at least five in New York, are suing prison systems and claiming that they are being denied treatment. Last year, a federal judge in Kentucky ordered prison officials to treat an inmate at a cost of \$25,000 a year. Kentucky prison officials had not provided treatment, saying it was unlikely to be effective.

The case of Edward McKenna, a 55-year-old New York prisoner dying of the infection, shows the charged debate that surrounds hepatitis C. Mr. McKenna, who is suing the state, is accusing prison doctors of denying him treatment that could save his life.

"In a roundabout way, they're tell-

"We don't know" the parole board will do."

Prison officials produced a document on Thursday from Mr. McKenna's medical record that quoted him as telling a doctor he did not want treatment for hepatitis C. Mr. McKenna, they added, also had to be counseled to take medication for severe emphysema, and was a poor candidate for hepatitis C treatment.

Mr. McKenna denied both claims and cited 10 documents in his medical record that he said supported his version of events. When asked to provide copies of the documents on Friday, prison officials said they did not have enough time to locate them.

Mr. McKenna's infection has progressed to full-blown liver disease. Most doctors agree that once the disease reaches that level there is no point in treating it. Mr. McKenna says he is willing to try anything at this point. He has lost 50 pounds.

"As long as I'm breathing, there is always hope," he said.

The men and woman guarding Mr. McKenna also fear the infection. Peggy Porter, health and safety coordinator of the New York State Correctional Officers and Police Benevolent Association, said that a half-dozen officers have recently reported being infected by prisoners. The officers, she said, do not make the infections public out of fear they will be stigmatized.

Glenn S. Goord, commissioner of New York's correctional department, said the state was addressing the problem aggressively, as it has with other medical problems. "We're committed to providing the best constitutional and community standards as we can," he said, referring to treatment. "The governor has asked me to do whatever is appropriate to protect my inmates and my staff." Prison officials say only one guard has reported contracting hepatitis C and there was no evidence that it came from an inmate.

Doctors agree that having so many people infected with the virus incarcerated creates an opportunity for education. Infected inmates — the vast majority of whom will eventually be released — must learn how not to infect others before returning to the community.

But the debate over the costly new treatments continues. New national guidelines for treatment are expected to be released this fall.

Dr. Anne S. De Groot, a Connecticut prison doctor and editor of a newsletter on infectious disease in prisons, said prisoners with identical illnesses were being treated differently in different states. "If you're in Pennsylvania you will get treated, but if you're incarcerated in other states in the Northeast you will not," she said. "It's ridiculous we don't have a standardized approach."

Pa. 3

CONT. PG. 3

EXH. J

TRANSCRIBED FROM WRITTEN JOURNALWilliam M. Clark

- 8/31-- Consult scheduled--was not on call-out. Saw her last roughly 2 weeks ago and told blood would be taken to do viral lode and last consult before treatment. Frustrated & angry--supposed to contact parents tonite, let them know what's up. Sent request w/inmate to Egglar same day.
- 9/7-- no request answered, no consult scheduled today.
- 9/8-- received request back scheduling me for 9/12.
- 9/12-- told my alpha feta protein was high(71.5) and after consulting notes on sonogram and checking my testicles for lumps, Dr. Egglar told me it's just from the HEP. C-viral load-678,000,RNA-3.5 HIGH.
- afterward talked to another HCV infected inmate who gave me this quote from a letter sent to the medical personnel by the doctor who saw him. This letter from his medical file was written by Dr. Donald F. Mandetta of Internal Medicine Associates-1850 E. Park Ave., State College, Pa. 18603, stated, "An Alpha-Fetaprotein is a reasonably reliable tumor marker for hepatoma." This worries me as Dr. Egglar passed it off so lightly & I won't get any more tests for approx. 3 months,(Drs. words) Put on medical lay-in for 2 wks. to see how I react to treatments which will start on Friday-9/15/00-signed a release form informing me of all side effects, including death. Mentioned that if my psoriasis got worse after starting treatment might be a reason to get a liver biopsy. When I asked w/out treatment, Dr. Egglar informed me I had 3-5 yrs. before liver failure.
- Fr.9/15--started treatments today!! been 6 hrs., just feel a little anxiety, clenching jaw. Horrible, constant throbbing headache tonight, off & on nausea, went thru terrible chills for a few hours. Itchy.
- 9/16-17--Don't seem to have any real ill effects from ribavarin. Itching continued, esp. bad at night.
- 9/20-- requested sick call today, last blood results are worrying me badly. May have jumped the gun, was informed this morning of lab work being done today. (Dr. Egglar hadn't informed me she ordered any.) Checking for platelets and general HEP. C blood tests. No alpha feta protein check.
- 9/25/00--went to sick call, requested that alpha feta protein test be added to bloodwork; denied, the P.A. said he would stick to Dr. Egglar's plan for alpha feta protein to be checked in December, that sonogram had showed no lumps or masses on liver. He could not order a biopsy. Did extend med. lay-in til 9/28 when I'm scheduled to see Dr. Egglar. Having a problem w/ diarrhea, don't want to be in the middle of nowhere with that problem.
- 9/28-- saw Egglar today--ALT's are down, informed that platelets are dropping seriously; before treatment was low, 129K, 1st wk. of trtmt. 93K, 2nd wk., 72K. Will check bi-weekly, if too much lower would have to get steroids or possibly stop treatments. As far as alpha feta proteins, doesn't feel worried enough to take any more tests at this time. Will screen for them in February,01. ALT:63
- 10/2/00--things bothering me since starting treatment, not real noticeable at first but starting to concern me. Blurred vision, lightheadedness, and pressure on my left side of stomach which actually gets painful. All these symptoms don't last long but are happening 2-3 times a day. Could weakening of my immune system brought on the psoriasis? Seems

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to be improving slightly in some areas. Won't send me to dermatologist, turned down last 2 requests. This is a major concern to me because I have it on all my joints, including my hands and it cracks and bleeds constantly. *They stopped sending me to Dr. Dunne about the time of my HEP. C diagnosis.

10/6/00

2:20AM- Becoming an every other night occurrence. I itch so badly I wake out of a dead sleep. I mean from head to foot, it keeps me up so long some nights I get headaches and am too tired to work the next day. Am told it's the HEP. C, makes me wonder just how long I've had it since I've had a problem with itching for approx. 13 yrs. now. I used to go to sick call for itching while doing my original sentence in 1986 or 1987. Not being filled in about diet pisses me off because now that I know it effects me there are certain things I can try, for instance, this was an every night occurrence during part of the summer and I stopped eating ice cream. The itching subsided. Lately I think onions might be having a bad effect on me, this is no science going on here but its all I have. When I tell Dr. Egglers this stuff, I'm told we can't test for that, just use trial and error. In the meantime, I'm suffering, it gets maddening when I itch on my scalp, by my eyes, in my ears and nostrils and the worst of it being anywhere I'm affected by the psoriasis. Many nights I scratch so bad I rub it open and bleed. Right now I feel like screaming in frustration.

10/5/00- Thursdays are Dr. Egglers day to see HEP. C infected people. Although I was told last week that I should be checked bi-weekly for all my counts (HCV related), she said she wanted me checked again this week because of the platelets dropping. I waited all week so she could consult me today. I was informed this morning that I was to have lab work done at 9A.M. so I knew I wouldn't be seeing her today & will probably have to sweat out this whole week to find out if my platelets are rebounding. My platelets are what make my blood coagulate when I bleed and this fact is very upsetting. My gums bleed occasionally because of receding and just wondering sometimes is my system working or am I going to just bleed away some night when I am sleeping.

10/10- saw Dr. Egglers today, my HGB is still low but better than last blood work (3.9 from 3.5). PLT's dropped but leveled from last screen-70K. Told her about itching, giving me 50mg. ATARAX. Did not test my ALT's this time around. Told her about psoriasis getting bad on my penis, she put me in for another consult with dermatologist, Dr. Dunne. Informed of headaches and pain in stomach. Was upset down there today, they schedule 5-6 guys for one time knowing she keeps us there 20-30 minutes each. Was sick from medicine; headaches, nausea and tired & irritable from 3 nights of itching, not getting proper sleep. Lost 5 lbs. in last 2 weeks, asked for snack bag. She told me just eat everything else when I said they always have lunch meat in those bags. Trying to keep meat intake down because of high iron count.

10/15- Thinking about last consult, Dr. Egglers noted improvement in psoriasis on my hand and I had to point out that its not better or worse, its the same. Still haven't gotten my snack bag. Giving me 50mg. Atarax for itching & to help sleep.

10/18- asked about the snack bag this morning at treatments, told by Candy it would be awhile because they now go to Harrisburg (Camp Hill?) for approval. Then told it would probably get denied, they feel we

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should get nutrition at commissary. I've never been sat down and told what my nutritional needs are.

10/20- It's 2:05A.M., this is the 3rd night in a row I've waken up out of a dead sleep, usually from the itching. It's maddening. Ever since mom sent the book, "Living W/HEP. C- A Survivors Guide" by Gregory T. Everson, M.D. (Dir. of Hepatology, Univ. of Colo.) and Hedy Weinberg, a hepatitis C patient and writer, I get more informed by each line I read about this disease. According to the book I have a few symptoms of advanced liver disease. There are things they should be doing, a biopsy primarily, but even the blood tests I've been given should be being followed up. * All I know is that there was a sudden rush to start me on the interferon & ribavirin in June-July, 2000 after months & months of the attitude that "Your only slightly elevated (ALT's), you should wait, we'll test every 6 months", when out of the blue my platelets became an issue. Now it was we better start you soon before they go down to the point its unadvisable to treat. The book has made me very angry because as I understand this disease more, I'm realizing how much they (D.O.C., Wexler) are only concerned about their bottom line. A lot of guys get a bag lunch as a snack for the evenings in case they get hungry. I put in for it because as others have had happen, I lose my appetite some days, today I only ate breakfast at the chow hall. This evening I ate a couple bags of noodle soup w/veggies thrown in and an apple w/peanut butter. 2-3 months ago I didn't miss a meal at the chow hall & this has me scared. They give us the multi-vitamins but then I read that the itching could be helped w/other treatments to create bile. They don't mention that, they want to give us benadryl or stronger if needed. Mine got bad enough that I was given 25mg. Atarax, then 50mg. Atarax. All it's doing is making me pass out. The latest at night I can get this (at the meds. window) is 7P.M. Some nights it makes me pass out at 9 & I'm up again at midnight. I've even taken to sneaking the pill out so I can take it more closely to my bedtime (its a misconduct but what am I supposed to do?) Even at that, as tonight, I got 3 hrs. and here I am. About the vitamins, I have to mention this because its just one other thing that has me so pissed off. Nobody says anything to me about iron being bad for me until a test shows it to be high(75?) For years I'm buying the commissary vitamins and they are full of iron. This happens somewhere bet. May & June, when I'm also finally advised I should cut down on red meats. I'm eating this stuff for yrs. that they don't tell me I've got HEP. C, but then after they give me the diagnosis it takes 6-7 months to get around to telling me this new info. Now I wait 2 wks. each time to see Dr. Egger and I have questions & concerns, I'm getting numbness on the tips of my fingers, my joints ache even after just walking the yard 2 times. Up to 2-3 months ago I used to play handball everyday for 2½-4 hrs. per day. I got laid in from my job because I'm too tired in the morning and somedays I get diarrhea & don't want to be out in some field when it happens. My psoriasis is another reason because it becomes very tender since starting the treatments. It's especially vulnerable to the itching and all I have to do is bump it and it cracks and bleeds and is painful. I wish I would have started this journal a year ago when I was first told but I didn't feel sick then. (I got fatigued easily, I could pass out for 2-3 hrs. after working all day or playing handball, but I thought to myself, your getting older man, this shit happens), and I wasn't aware of where this was going to go, the med. dept. was great for giving us guys these pamphlets about how only a small fraction gets really bad. Then I read a line

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from this book and I quote, "We now know that approx. 85% of patients become chronically infected." The more I read the more I become frustrated at this whole system. At this time I'm completely confused and ignorant to where I stand with my disease. They completely ignored my disease in 1992 and downplay it to this day. They'd still be ignoring it completely if it weren't for guys like Rob L. As I stated earlier about this journal, I do not want to fake it and start from Oct. 1999 when I was 1st told, as I said, I didn't realize what was coming, and even after that, I think shock and trying to cope kept me from starting this earlier. What I am going to do in the next couple of days is recollect as best I can the day I was told up to the time I started writing this. Even at this rate, I'm missing so much(because I do try to normalize some parts of my life, socializing, playing cards, going to the yard, reading), that I don't get alot of stuff down here. Thoughts like tonight, when alot of times I'm just too tired to sit and write.

10/23-- overslept this morning, they had to call for me to get meds. Bob S. told me recently that they were giving him 2 different kinds of interferon, told me to watch how it was coming. I've been getting it in a thin syringe w/light blue cap. Today it was in a thicker barreled syringe w/orange cap. One of the warnings on the ROCHE companies ROFERON label states that these interferons should not be mixed. I'm concerned with this new revelation. How are they going about buying the meds? How many different kinds of interferon are they dispensing?

10/24-- Definately a difference in meds(interferon). Some of the effects I haven't had since I started treatments, when I thought I was getting the orange cap. Feeling very hypertense but at the same time physically exhausted. Slept pretty good last night, still slept for 3 more hours after taking meds. this morning.
Concern: On Friday(10/20/00) evening med. line I had one of the nurses ask why I missed my meds. that morning. I did not miss meds. because on Mon., Wed. & Fridays I get my interferon shots also. Now I notice their not always marking when I get my meds. I admit I've missed my ribavarin twice since I started, once in the morning and once at evening meds. Both times I was sleeping.

10/25/00

Wed. AM-- Told they are out of interferon this morning, I noticed they had the orange capped syringe meds. and asked for that. I was told that that was something different by Candy. Informed I'll get interferon tomorrow and Saturday.(see highlighted area on Roferon-A info sheet they gave us).

10/26-- got interferon, informed I was to see Dr. Egger. They never took blood last week so no tests to go by. When I informed her of tests she sent me right to the lab for bloodwork, told me to sign up for sick call for results tomorrow morning. Told her after reading book I had some questions. As to what phase of the Hepatitis I'm in, she couldn't tell me. When I asked about a biopsy she first said the book's a year old, that they don't have to biopsy because lab work correlates with prognosis(but she can't give me a prognosis). Then said I couldn't have a biopsy right now anyway because of my platelet level(going by blood from 2 wks. ago). Informed dermat. consult was turned down and that protocol stated she should have been informed right away and wasn't, also no back-up was given to her. Told her I was going to complain to Larry Lidgett & she told me that would only create problems for myself & her, that I should give her a chance to get them to change their minds. When I told

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- her the book repeatedly mentions biopsy, she said she would have never recommended it because it's wrong, that the doctor who wrote it is a hepatologist and that's what he does.
- 10/27- Asked C.O. if sick call had been announced, informed they got a call earlier, no sick call today, as it's an in-service day for employees.
- 10/28- bad night last night, itched until I made my psoriasis bleed on my lower leg, got nervous about my platelets because it took awhile to stop bleeding. Went to get my interferon this morning and there were the orange cap syringes. When I mentioned it to him, said it's the same stuff, just that one comes pre-filled in the syringe, the other doesn't. I asked if they were made by the same company, he said, "I think so, no, maybe not, no there not but it's the same stuff as I would usually get."
- 10/30- bad night (itching)
- 11/2/00- Brought a list of questions for Dr. Egglar today. First I was informed that within a half hour ago she got a memo from someone at Camp Hill denying my request for a bag lunch. Dr. Egglar doesn't understand the denial as there is no HEP. C diet here and she stated that I am losing weight (she noted on the memo) & she told me she would push for "Resource" nutrition drink as an alternative. She told me she felt their decision was "harrassment" on their part concerning me. She has put in a high protein/high calorie diet w/ instructions to keep meat intake down because of my high iron count. She then informed me she hadn't gotten an answer on this last request for me to see Dr. Dunne, the State College dermatologist. No alternatives have been given yet but she feels they may get us on tele-med?, she was also going to call him today. She then stated that she feels if I continue to push for this dermat. consult, that they are going to say that if I can't tolerate the psoriasis, they would stop my interferon treatment on the grounds it's making it unbearable for me to function. Not long ago she was looking at my hands and saying they were improving. I live with this stuff and it gets worse after every summer because I can't get the exposure from the sun, which improves it greatly every year. It has spread to other parts of my body since treatment began but my main concern is my hands and this was on-going approx. one year before I started any treatment. I also asked her about receiving Ursodeoxycholate (URSODIOL) for itching and she said something to the effect that that book was going to end up getting her in trouble and she didn't want to lose her job, but she feels these meds. are only a last measure for decompensated liver patients because the drug is toxic and the test results are not there to convince her differently, will not even think of prescribing this med. Asked about genotyping & she said that should be done before treatment starts (it wasn't), but that most HEP. C cases are genotype 1(one) and that that is the correct treatment being given to me. She then ordered a new lotion I inquired about for my psoriasis-AMLACTION-12%. My weight is 182, so I lost another pound this week. Lab results from blood taken yesterday are: ALT-55, AST-55, Alk. Phos.-161, GGT-55, Bilirubin-0.6, Albumin-3.5, WBC-4.5, Platelets-85K., HCT-37.3, HGB-13.
- NOTE: Spoke to (name of inmate deleted per request, AKA "Doc") on 11/3/00. He informed me that he had spoken w/Dr. Symons on 11/3 and he inquired of the doctor info. on Ursodeoxycholate, who looked it up in his P.D.R. and informed "Doc" that nowhere does it mention being toxic; also informed him that he didn't know how to use it prop-

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- erly pertaining to his condition RE:Itching) and that he would contact Dr. Mandetta (Internal Medicine Assoc. of State College) as to his recommendations.
- 11/5/00- Told by Candy at morning med. line that all bag lunches(except for diabetics) were being stopped. Signed up for sick call(lotion not in).
- 11/6/00- At med. line this morning heard from inmate that the bag lunches are back on. They had both (types) syringes out this morning, I got the orange cap one. (Wish I could find out if they are the same company). If they are though why have the pre-mixed and the other? Asked P.A. Billie Burke at sick call about bag lunches, there must have been another decision because she informed me that on the same day (11/2) that Dr. Egglar put me in for the high protein/high calorie meals, she stopped that request and re-requested the bag lunch (this is the same time she showed me the memo refusing me for the bag lunch and the change was in Dr. Egglar's notes).
- 11/8- Last few nights pretty good, woke up from itching for a few minutes and fell back to sleep.
- 11/11- Heard Vicky(R.N.) answering someone's questions this morning at med. line. When it was my turn I asked her if she was talking about the interferon because I heard her say something about the old stuff and the new stuff. When I asked, she confirmed: 1)that they were using one thing, then went to another, 2) that they were from 2 different companies. It seems like they have 2 stocks and when they run out of one they will use the other at times and sometimes they won't. (will change your day). I'm up tonight because of the itching, it's pretty bad. Got the bag lunch today, consists of an apple, 6 cinnamon (graham) crackers, a container of peanut butter and a pint of milk. Milk gave me awful gas tonight. Mom and dad were up today,nice visit -wish I could sleep so I don't look like hell tomorrow morning when they come back. Read article about the pegdalen, their getting great results, FDA approval early 2001. Wish we'd get it here, I'd stop this stuff in a heartbeat. Hate being tensed up and wondering if my psoriasis spreading is due to meds. Talked to Anthony M. today, told him about the article I'd read and I had to laugh because of the bullshit they tell you here. He told me that Dr. Egglar had told him in August that because his enzymes were so low that he should wait for the new med. to come out. This is what she was telling me before August and in August she made the statement that we wouldn't see that med. for years here because of "politics". This was when I was told I should get started on interferon/ribavarin for whatever reasons she changed her mind about , regarding my condition.
- 11/16- consult w/Dr. Egglar today-2nd in a row they didn't do all the blood work. Did more today & I'm supposed to sign up for sick call & get my platelets, etc. results tomorrow morning. Asked her about using different kinds of interferon and she admits they know they made a mistake giving some guys something else for awhile. Said there was nothing noted in my chart about that in my case(as though they'd put it on paper!). Told me as far as she knew I've been on Roferon the whole time, but I know different. Said I could write to Lidgett and ask him. (He's not going to admit to anything.) Was informed that the only iron count I've had was in Feb.'00-52 HIGH, not 75 as for some reason I believed. Never told about it until August(found a consult note) when I was finally informed of the vitamins sold here and the meat intake. (not June-July as stated earlier) Told her itching is just as bad when I suffer from them, but at least it's not every night. She said yes to my request for a higher dose of

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ATARAX (50mg. to 75mg.). Also said we should be getting flu vaccine and I should get one. My counts really disappointed me today, the counts they did have as compared to 11/2 consult had gotten worse. ALT-59, AST-58, GGT-55, Alk. Phos.-159H., Bilirubin-0.7, Albumin-3.8. I was real disappointed at the enzyme levels, now I'm worried I'm not going to respond to treatments like quite a few other guys are. Next consult-11/30.

- 11/17-- gave me the rest of my results after getting my shot this morning, these results are better than last consult (enzymes). If I didn't mark my HCT wrong on 11/2 that is the best improvement so far (37.3) and platelets up-90K, WBC-4.5 is same. I don't understand decimal thing by their count, book has it as straight numbers, need to ask about that because if 4.5 was right compared to book, I'm in serious trouble-(normal range, over 6000, serious abnormal range, under 3K), HGB-12.2, RBC-3.57.
- 11/21-- Was told at 4 o'clock meds. that when Dr. Egger upped my Atarax to 75mg., she also changed "as needed" to 8:00P.M. med. line. Told to get on sick call, that P.A. would change that. Got ribavarin. Went back at 8 P.M. for Atarax. Signed up for sick call on block.
- 11/22-- Went for shot this morning, saw P.A. Finn, who asked if I just wanted med. times back for Atarax. She said she would note it on my chart. Also asked about possibility of getting shots in the evening, was told to see Vicki(R.N.) at meds. window. Also got more lab work done. Noticed lab checklist noted was for different things than usual and lab tech. said one was for thyroid the other was a number, (3514?) and he couldn't find the test that matched that number. After he took blood I happened to glance at the sticker he was putting on the vial and it was lab work for an A. Clark, I think it was an AS number and I told him he had the wrong guy's lab work. He then got my blood request out and it was the Liver Profile, iron and ferrin. Went to 4 o'clock meds, refused Atarax, said there was no changes made, would have to go to 8P.M. meds. Did not go to 8P.M. meds., not feeling good, like a touch of the flu, decided I'd try to go without Atarax instead of walking around in 17 degree weather. Really, big mistake, was up most of the night itching. Forgot this the other day when I spoke to Billie Burke, was told Dr. Egger had changed my consult to 12/5.
- 11/23-- this is fucking incredible, I went to 4 o'clock meds., got ribavarin and when I asked for Atarax, was told by Katie that my prescription had run out. Informed her I saw P.A. Finn the day before and she had noted my chart. Katie said I was out. How the hell can this stuff be going on? The ineptitude and lack of concern is really pissing me off, it's after 1 A.M. and the itching is driving me crazy again tonight. It doesn't stop. I didn't sign up for sick call but I'm going to say something in the morning when I go for my interferon shot. Really considering putting a grievance in because this is so bad I want to cry. Making a list of questions I want answered tomorrow, especially a request to see any doctor and ask why I can't get the medicine that may make the itching subside(as outlined in my HEP. C book). These Atarax to make me pass out can't be good for my liver (why my enzymes are rising?) Really feeling frustrated and angry about all of this. Already exhaust easily and now with the itching again at night, I'm exhausted and run down all day. Guess I'll watch TV and hoping to God I just pass out. I want to scream! My back's been locking up again recently from fall in the kitchen here a couple of years ago. Don't have the energy to exercise like I used to. Got to the point itching was so unbearable I went to C.O. Wertz

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and asked him to call med. dept. He came back to me a few minutes later and told me (forget name he said) that my prescription had been updated on 11/22, but there was nothing they could do at this time in the morning, that I should let someone know what's up at morning med. line.

- 11/24-- Got my interferon, was told by C.O. on block I had lab. (that was a mistake)+Waited an hour to talk to someone about Atarax mix-up. Betsy went to my file and informed me that yes, it had been renewed by Finn on 11/22, to expire on 1/11/01 and that Katie had probably read the 1/11 as 11/1. For that I lose 2 nights sleep. Going to try and get some sleep til I get my flu shot at 11.
- 11/25-- exactly what happened at med. line when I explained to Katie everything I'd been informed of. She looked in the log-in book and then apologized.
- 11/25-- stayed active all day, walked the yard, an hour after Atarax slept thru the night.
- 11/26-- slept really good.
- 11/28-- last night was really itchy, if it hadn't been for Atarax knocking me out I would have had a really bad night. On sick call tomorrow morning, get lay-in reinstated til I see Dr. Egger, get blood results from early last week.
- 11/29-- got shot, saw the best P.A. I've been in contact with so far, (new guy, mid twenties), wrote all my results down for me & explained what each meant (see lab notes). Iron is high! He said looks like anemia except for Total IBC is normal. Says runs in some families or could be meds. He also reinstated my medical hold-in for work, which should open the door for me to get a block worker's job, my hands can't take the prolonged cold weather with cracking & bleeding. They have improved greatly since the 6 wk. hold-in.
- 12/4/00-- read info. from American Liver Foundation, explains iron in liver (high amts.). Possible hemochromatosis? Association with diabetes? Autoimmune hep. or viral hep.? Also read they do have treatments associated with itching & bile products in the skin. Going to bring this up to Egger Thursday. I want tests done. Metallic taste in mouth all the time, exhaustion getting worse, get nauseous, light-headed, hands tremble real bad, getting chills again. The A.L.F. says early treatment is best thing, this is really bad how we get treated here. Not treating my problem, treating side effects by using Atarax to pass out. I'm sick of it.
- Tues.,
12/5/00-- had consult w/Dr. Egger this morning, didn't have results of last blood work to see how my enzymes are. Told to sign up for sick call again this week (3rd in a row) to get results tomorrow morning, that if she saw anything on them later today she'd call me back Thursday. She seems to downplay my iron count, said at some point I'd be a good candidate for phlebotomizing, Asked if I would be tested further, answer, no. Asked about possibility of hemochromatosis and could I be tested for that, answer: with hemo. would phlebotomize, without hemo. will probably phlebotomize. Asked about metallic taste in mouth, told that's the ribavarin. Asked about nausea, trembling hands, she said it's the accumulation of the treatments and I'd be fine in a month or so. Told her P.A. had told me to ask about family med. history because of possibility of anemia. I tried to explain that to her, she told me that the blood work shows no signs of anemia. Asked about treatment for itching AGAIN, told there is no treatment, that the URSO. is for people with decompensated livers

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only and told me, (NOW GET THIS), that if I came up with a treatment she would consider it. Told only treatment is what I'm getting now (ATARAX). Told her I've been exhausted lately, sleeping too much, she told me I didn't look good, that maybe I should try getting treatments in the evening. Asked her if the flu shot could have affected me and she said that was possible. Asked if I was getting the 75mg. of Atarax, I said yes, and she summed up the itching situation with the same old scare tactics about stopping the treatments. Told her my nose has been extremely dry at night, so much so that my nose is full of blood in the mornings, she prescribed a nasal spray. Supposed to make a decision about time of treatments by sick call tomorrow, will probably try it. She also informed me that she'd read new info. concerning my alpha feta proteins and that they only had to be concerned now if they got up to the 400 level (one time count for me was 71.5HIGH). Asked if I was using the creams as itching can be caused by dry skin, which I realize, but this is itching like I've never known, and I feel they know this, I read the same info. she does, I'm not making this up. Why don't they want to treat problem? Cost? Is that a factor? Really, really disgusted with idea of having to be knocked out to get a good nights sleep, knowing if it (Atarax) doesn't work, I'm up for the long haul, which is why I'm writing tonight. Itching woke me up out of a dead sleep 2 hours into it tonight.

- 12/6-- Went to med. line this morning, then to sick call, informed by P.A. Finn that lab results weren't here, she said there's been problems with the lab faxing results. Going to put me in for treatment time change.
- 12/8/00-- Sick call this morning for results of 12/1, wish I knew what's going on, everything fluctuating, ALT's & AST's slightly down, platelet's dropped again from last work. Will start interferon at evening med. line starting Monday, 12/11. (See lab results for 12/1.)
- 12/10-- up with the itching again, meds. don't help when I have to take so early, I pass out early and then I'm up in the middle of the night when itching is particularly bad.
- 12/12-- itching bad again tonight, bad night sweats.
- 12/14?-- saw Dr. Burke today (Psychiatrist), not sure why he had me on his call-out. We talked about slight depression I feel. (he said that's normal under circumstances) He's going to note that I don't Atarax as a psychotropic, so he has no problem with me getting my prescription at one time instead of going to med. line and having to take it early. Told him about concerns regarding my high iron count and fluctuating blood counts.
- 12/16-- itching so bad tonight, woke up in the middle of night, I was soaked with sweat.
- 12/17-- up again tonight itching, really frustrating, bugging me about Dr. Egger saying if I come up with a treatment for it, let her know. The fucked up thing about it is I am trying to get more info. on it. Seems the only way I may get help is to find it myself. Wrote to C.D.C. and American Liver Foundation.
- 12/19-- woke up last night, sheets were soaked. Itching bad but got back to sleep.
- 12/20-- sheets soaked again last night, looked up sweating as side effect of interferon (5% get it). Am going to push for more testing on iron, really don't like answer I got on that and am really getting concerned about weight loss. I know it's mainly because of cutting back on meat and not being able to eat many of the alternate meals. Can't

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get tofu eggs to go down, feel like I'm going to throw up. A lot of soy meals taste so bad I can't eat it. As far as testing goes, if she continues to deny me I'm going to put more grievances in, even though I'm afraid to do anything because of threat to stop my interferon. I will refuse to sign anything stopping my treatments as long as ill effects aren't worse than they already are. I am going to make another list of requests for next consult with Dr. Egger, it just gets so frustrating I haven't even bothered lately. Always I feel like I'm getting the runaround, have no problem giving me stronger meds. to sleep, solution for dry nose, but when it comes to any real testing, I always get the runaround and/or that always present threat of stopping my treatments.

- 12/22- Itching bad tonight, will not let me fall asleep.
- 12/24- no blood work being done, just realizing she didn't schedule me for 3 wks. since last consult. Noticing little veins popping up on lower legs.
- 12/25- told my interferon is new stuff by Bonnie, have no idea what that means, asked for company that makes it, didn't know.
- 12/26- told prescriptions for Motrin & benadryl ran out, really pisses me off because Dr. Egger really pushed my next appt. back so far.
- 12/28- itchy, will probably ask doctor for stronger Atarax, going to have to make a list of questions for her, am really fed up not knowing what's going on with iron levels & my other results bouncing around
- 12/30- been thinking about the last couple of months, how I've lost 11 lbs since starting treatment, how I don't do much more than paperwork anymore, haven't been to the yard in 3 wks. I hate feeling this bad all the time, listless, getting tired so easily. The fear about what's going on inside me and the frustration of not getting answers is depressing me. I'm also angry about being pushed back to a 3 week break in consults with Dr. Egger. I have a lot of questions, about what's going to be done about my iron count, about the loss of weight and a diet I can live with, can I get Resource drink and primarily, being put back to seeing the doctor every 2 weeks, there's too much info. I need to be seeing her less than that.
- 12/31- I'm hoping and praying the New Year brings a certain amount of health back to my life. Trying to keep my head up, won't back away from asking for what I need this year and will do whatever I need to do if I don't get the right answers.
- 01/03- Saw a Dr. Eidsvoog today. Got to ask a lot of questions. I ordered a Liver Profile since it's been a month. Was going to start phlebotomy until Dr. Symons came in and said to wait until March when my treatments are at 6 months. She (Eidsvoog) was very concerned about alpha-fetoprotein level and ordered another test (this goes completely against Dr. Egger's last consult when I was told those levels were acceptable). Dr. Symons turned down Resource request, said I didn't fit criteria. Pressure on both sides of stomach could be build-up (ascites). Asked for a biopsy so we know what stage of Hepatitis I have, she said the higher up we were worried about effects of a biopsy, that bleeding internally was common (from everything I've read, it sounds like a relatively safe procedure). Can not tell me how extensive liver damage is. If alpha-fetoprotein levels rise, will order a new sonogram to be done. Agrees iron is high, but Dr. Symons feels I should wait until interferon/ribavirin (I/R) treatments are done to start phlebotomy. Also told I am anemic and was before I/R. Order

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Cholestyramine for itching. Forgot to ask about what tests of bile flow and if possible to get Atarax dispensed so that I take it closer to my bedtime. She told me to eat beans alternative protein if trying to cut down on red meat. Dr. Symons says I need the protein, down-plays me cutting my red meat consumption (all these different opinions get very confusing). Egger says I should cut back.

01/06- Got Cholestyramine today (Prevalite), I'm itchier than usual. Itching usually doesn't effect me during the day.

01/07- Itching bad again tonight, "Doc" says the stuff takes about weeks to start working.

01/08- Itching real bad again tonight.

01/09- This is every night again, Atarax doesn't even seem to help.

01/10- Scratching open my legs again (the psoriasis), got a packet of info from the Department of Health and Human Services today on different things I inquired about. Read about Hemochromatosis, they will test for it but it really has me concerned because a high iron count is bad whether I have it or not. Can cause arthritis, heart problems, hepatitis, can be fixed by phlebotomizing, has to be done a lot over time to get the levels back down. Really pissed that I just blow this stuff off. I'm going to ask that the procedure be done soon. I really can't understand why they'd hold it off, they do the extra blood tests and watch me it would greatly improve. I know they don't want to get into this and once they start it would have to be an ongoing thing. Never got called back down about my results, I don't know if that's good or if anyone has even looked at them. Got an updated Chronic Hep. C pamphlet they're updated effects of Ribavarin and it can exacerbate psoriasis.

01/11- Same thing tonight, scratching away.

01/12- More of the same tonight, terrible tonight, can't get comfortable. Can't stay still, it's tearing me down, gets so frustrating I want to scream or cry. Will put in a sick call request for Monday morning. Went to yard today, played one game of handball and so winded I could not get my breath. Pamphlet had a nutrition chart for high iron, eating right at this point wouldn't help me even if I could eat right, have to get my levels back down to normal. Going to demand it. Laying here and scratching at myself. I know I shouldn't be but I can't help myself. Just want sleep. Found out through pamphlet that ferritin is iron stored in my liver and that excess iron tears the liver up, that's definitely a concern to me as it's actually in my liver which is already screwed up (Dr. Egger tells me I need only be concerned with level which is only level that is in normal range). The National Digestive Diseases info states if ferritin levels are high must get these levels down to low end of normal. As of 11/24/00 results Ferritin is 734 and the norm is between 19 and 370.

01/16- Went to sick call this morning, saw PA Kimmel. About phlebotomizing, she was going to talk to Symons and get back to me she said Eidsvoog noted some concern about my RBC being low, and also. Eidsvoog was ready to start the treatment and just monitor me closely. Symons nixed it until February. I'm ready to get it done because it will bring my iron count down. I hope I heard alpha-fetoprotein count right, that dropped dramatically. Blood work results were: ALT-54; AST-50; HCT-34.2; RBC-3.42; HGB-11

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Platelets-101,000; Alpha-fetoprotein-22.8. If Dr. Symons Dr. Eggler don't get back to me in a few days, I'm going to put grievance in. I'm also going to start requesting the new Pegola Interferon as soon as I know it's been approved by the FDA, as doesn't look good for me as far as the results on my blood-work goes concerning my combination (Interferon and Ribavarin) there is going. Test results are showing improvements with the Pegola for people not responding to the combination therapy available n

EXIT. J

- UPON RECONTACT
- 3/20/92 blood test taken - ALT + AST HIGH - NOT TOLD OF ANY PROBLEM
- RELEASED 9/6/92
- 9/15/95 ^{recommitted} blood taken - levels normal except lymphocytes (HIGH)?
- 11/7/96 " - HGB + HCT HIGH - not informed of any problem
- OCT., '99 ^{after 2 mos. of} getting exhausted easily, some abdominal pain, ask for HCV + t tests.
- 10/20/99 - HCV POS. - MARY JO INFORMED me that I'd had HEP. A + B. then off & probably had chronic HEP C because blood work in 1 high enzymes. Got very angry & asked why they wouldn't have something about that. No answer to question. Asked about treatment was told by Mary Jo they would not treat because ~~was~~ enzymes only slightly elevated & that condition would have to get a lot worse to see Dr. Symons on unrelated matter (psoriasis). At that time noticed blood test results & gave me some info. on HCV. No to 2
- 11/99 - grievance - refused treatment, biopsy & viral load - all reviews of grievances were upheld.
- 12/1/99 - also saw P.A. Finn & requested follow up blood work, told levels don't. that much & next test would be in 2 mos. (April, 2000)
- 1/2000 - consult. w/ Symons, asked about viral load (important factor in HCV) not important - not a big deal because enzymes only slightly elevated
- 4/22-24/2000 - lab results iron high (not told) ~~but~~ bilirubin high, enzymes a
- 4/2000 - started seeing new doctor, Dr. Egglew - told me need to start treatment til next yr. when pegolated interferon is available.
- 6-7/2000 - started getting called to med. dept. alot - ultrasound ordered, results. liver & spleen consistent w/ chronic hep. and/or cirrhosis
- 8/2000 - Egglew informs me I should go ahead & begin treatment with interferon ribavirin (I/R). Told me ~~was~~ pegolated would probably be approved FDA in Jan., '01 but because of "politics" wouldn't be getting it soon, also informed about high iron counts in FEB. results.
- 9/12/00 consult w/ Egglew; alpha feta protein high (marker for cancer),
- 10/1/00

- Told me if I came up with a treatment, she would consider it. Nose full of blood in mornings. Told her I was concerned with alpha fetoprotein level, she said no concern unless reaches 400. My level is 71.5 which is above the norm. told pegylated available.
- 12/6/00 sick call - informed by P.A. Finn lab results not in.
- 12/14/00 on call out for Dr. Burke, discussed depression I'm feeling.
- treatment cont. - ^{little} veins popping up on lower legs.
- 12/25/00 - to by Bonnie, R.N. ^{intuition} I was new stuff, couldn't tell me who made it. Depressed alot about frustration of not knowing what's going on with body + lack of answers from med. staff.
- 1/3/01 - saw new doctor today, DR. EIDSVOG - ^{ordered LIVER PROFILE (hepat)} wanted to start phlebotomy until Dr. Symons came in + said to wait until I/R is done. She was concerned about alpha ~~fetoprotein~~ ^{fetoprotein} levels, ordered another test. Symons request for RESOURCE drink, didn't fit criteria. Pressure on both sides of asked her for biopsy, told by her that higher ups were concerned w/ winter (from everything I've read sounds like a relatively safe procedure) Couldn't me how extensive liver damage is. O'Keefe ~~asked~~ ^{more} about high iron. the damage it ~~can~~ ^{is} can do to the body, incl. the liver. Also that high iron has negative effects on I/R treatment. Asked Dr. Symons about that + he agreed this pain + now being told that iron counts could ^{have affected} ~~be affected~~ treatment.
- 1/6 itching horrible
- 1/10 got info from Dept. of Health + Human Resources, read how bad high iron is, request for phlebotomy, denied, do then after treatment
- 1/01 → blood counts low, enzymes declining slowly. Got info from the American Foundation which states high iron effects the ability of interferon to do its. Dr. Symons about that again and he agreed.
- 2/28/01 - Eidsvoog asked what high alpha fetoprotein could mean for me, told cirrhosis of the liver, Eidsvoog + Symons made decision not to continue I did not reach undetectable levels. Asked about pegylated interferon, be approved by FDA in June, 2001
- 3/01 - ^{already on} ~~that phlebotomy~~ 15th Thursday in March to start phlebotomy, blood count 2000 ^{g/dl} started following Thursday. Eidsvoog, advised that high iron can

pegylated
approved by
FDA in June
2001.

Ordered another alpha-fetoprotein test. Refused me another ultra
 Refused test for dengue.

4/5/01 Telling me scheguan to help sleep. Taking these drugs concerns me,
~~seem~~ seem to be helping when itching is bad & wakes me out the
 next day. Refused an ultrasound & biopsy. After 4 phlebotomy
 level not dropping much & on Thursday 3/29? doubled amt. of bl
 and I went into shock. Counts low end of normal after 10-12 treatments.

8/7/01 Symons feels I should have biopsy, request denied. Biopsy request, alt. plan, doesn't
 last few months nothing changed, tried all the time abdominal pe
 severe at times. Told that with alpha-fetoprotein levels rising sh
 biopsy. Never happened. From this point the present how signed up for si
 ALT's - AST's back up. Viral load at 467,000. Continue to
 Liver Profiles but cannot tell me how extensive liver damage is
 Constantly asked for deam consult, refused. Pegylated interferon appar:
 PA Finnell will ask Dr. Symons about deam consult. DOC still not set up

5/2/02

5/9/02 Sick call - no ans. to above, PA Finnell will look into /consult w/ GONIS RD
 DE. STINE - PEGASIS

5/22/02 Consult w/ Dr. Symons, iron back up, will be phlebotomizing again

5/28/02 Consult w/ Dr. Webster - told itching was a lung condition, BILIRUBIN le
 elevated, asked for biopsy told possible complications were a deterrent to
 * met pg. told iron high again, would do phlebotomies BEFORE treatment (pegylate
 6/6/02 told him about abdomen pain & testicle pain - ordered sonogram. However got
 this day.

8/7/02 iron levels mid normal range - ~~started~~ supposed to start pegylated last
 7/31/02, reported to med. dept. told didn't have, started a week later. No bi
 or ultrasound done before starting treatment, can't tell me if meds will wor
 for me. Hope I am doing the right thing letting them stick this person?
 long body without having all the facts.

6/18 lab blood work cancelled

6/19 " " " 9:30 AM - postponed to further notice.

6/14 phlebotomy

6/19 " 9:40 AM - no one told me - cancelled til next day.

* 6/1 consult w/ Dr. Symons - told him about mucus, sonogram, he said will recycle.

8/12 consult w/ Dr. Webster - informed lab work from 7/2 - high asked why high, she said the cause is an autoimmune problem have been high for years. She wanted to change meds. something stronger, told her I don't like effects of steroids about sonogram, told if Symons ordered it I'd get it. He ordered months ago, have not gotten it to this day (8/17/02). Tine psoriasis for itching, informed her itching is everywhere in on face, upper chest, etc.

7/24 consult w/ Symons - told him about itching being so bad. I psoriasis, had to explain again that it's just a little worse on ps problem is everywhere. Asked to see an allergist, he told me I should shower every other day. Informed I'd be peg dated interferon on 7/3/02, couldn't find newest resal levels.

~~6/28~~

7/31

8/7 -

informed didn't have my peg interferon when called to med. started treatment, no sonogram, no biopsy, still can't tell extent of damage to my liver. Gave me a med. pass for for ribavirin which I'm to take everyday along with shingles Wednesdays.

8/13 -

when I reported for ribavirin this morning, nurse asked me w not taking my 2nd dose at 4PM. Informed him that no one had told me about a 2nd dosage. Had to wait til next day to see black sqt. wouldn't let me go to 4PM med. after making a cc the med. dept. & being told that I get meds in morning & self in evening.

PT

- also went to sick call this morning, mucus still really bad, checked lungs, said they were clear, that she could see it running

** - 8/10/01 - write 2nd grievance re: HEP C. peg. interferon a
1/01 - ask for it. - inform that high iron level may have effe
(Symons concurs) I also ask for a biopsy. Grievance be
way up chain of command. Told they genotyped me on
alternative to biopsy. That should have been done before my
of 9/15/00. Also made them aware of high dph. fatty proteins.
cancer

EXH. K

No. 01008558

CONSULTATION RECORD

Part A: To be completed by referring institution:		Type of Consult: <input checked="" type="checkbox"/> Initial [] Follow-up <input checked="" type="checkbox"/> On-Site [] Off-S	
Referred to: <i>lexford</i>	Referred by: (physician name) <i>B. Finn PA-C</i>		Appt. Date:
Specialty: <i>Genotype</i>			Appt. Time:
Drug Sensitivity: <input checked="" type="checkbox"/> No [] Yes (Specify)			
Copies of lab and X-ray results attached? <input checked="" type="checkbox"/> Yes No If yes, specify: <i>Consult 7/10/01; met 10/12/01</i>			
Reason for Referral: <i>Hep C Genotype</i>			
History of Injury/Problem:		Date of Onset:	
<i>Hepatitis C - DA 10/99 - but probably of long duration Tx w/ Interferon / Ribavirin. VL 678,000 → 267,000 @ 6 months. Treatment stopped @ that point d/t failure. Then treated for Ferritin > 80. C phlebotomy → Ferritin now 19. & Feboprotein 71 → 21 → 42.</i>			
Treatment to Date/Current Medications and Significant Medication History:			
<i>u/s @ for mass of liver 7/00 PLT 119,000 Imp- Liver biopsy denied. Alternate plan suggested 7/11/01 as AFP + genotype.</i>			
		<i>BRIDGET FINN PI</i> <i>B.F. PAC 8/2/01</i> Signature of Referring Physician Date	
<input checked="" type="checkbox"/> Approval [] Disapproval	Medical Director Signature: <i>For A. Hussain (MD)</i>		Date: <i>8/3/01</i>
Transmittal Date: <i>8/3/01</i>	Transmitted By: <i>JMM</i>		
Approval Date: <i>8/6/01</i>	Approved By: <i>JK</i>		
Part B: To be completed by consulting Physician and returned with officer to the institution:			
Diagnosis and Recommendations:			
		Signature of Consulting Physician Date	

Consultation Record
Commonwealth of Pennsylvania
Department of Corrections
DC-441

Inmate Name: *Clark, William*
Inmate Number: *A1 5585*
DOB: *9-11-54*
Institution: *SLE-Rockview*

EXH. 1

ROFERON®-A (Interferon alfa-2a, recombinant)

ROFERON®-A (Interferon alfa-2a, recombinant)

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis: Roferon-A has not been tested for its carcinogenic potential.

Mutagenesis: A. Internal Studies — Ames tests using six different tester strains, with and without metabolic activation, were performed with Roferon-A up to a concentration of 1920 µg/plate. There was no evidence of mutagenicity.

Human lymphocyte cultures were treated in vitro with Roferon-A at noncytotoxic concentrations. No increase in the incidence of chromosomal damage was noted.

B. Published Studies — There are no published studies on the mutagenic potential of Roferon-A. However, a number of studies on the genotoxicity of human leukocyte interferon have been reported.

A chromosomal defect following the addition of human leukocyte interferon to lymphocyte cultures from a patient suffering from a lymphoproliferative disorder has been reported.

In contrast, other studies have failed to detect chromosomal abnormalities following treatment of lymphocyte cultures from healthy volunteers with human leukocyte interferon.

It has also been shown that human leukocyte interferon protects primary chick embryo fibroblasts from chromosomal aberrations produced by gamma rays.

Impairment of Fertility: Roferon-A has been studied for its effect on fertility in Macaca mulatta (rhesus monkeys). Nonpregnant rhesus females treated with Roferon-A at doses of 5 and 25 MIU/kg/day have shown menstrual cycle irregularities, including prolonged or shortened menstrual periods and erratic bleeding; these cycles were considered to be anovulatory on the basis that reduced progesterone levels were noted and that expected increases in preovulatory estrogen and luteinizing hormones were not observed. These monkeys returned to a normal menstrual rhythm following discontinuation of treatment.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Roferon-A has been shown to demonstrate a statistically significant increase in abortifacient activity in rhesus monkeys when given at approximately 20 to 500 times the human dose. A study in pregnant rhesus monkeys treated with 1, 5 or 25 MIU/kg/day of Roferon-A in their early to midfetal period (days 22 to 70 of gestation) has failed to demonstrate teratogenic activity for Roferon-A.

There are no adequate and well-controlled studies in pregnant women.

Nonteratogenic Effects: Dose-related abortifacient activity was observed in pregnant rhesus monkeys treated with 1, 5 or 25 MIU/kg/day of Roferon-A in their early to midfetal period (days 22 to 70 of gestation). A late fetal period study (days 79 to 100 of gestation) is in progress and as yet there have been no reports of any increased rate of abortion.

Usage in Pregnancy: Safe use in human pregnancy has not been established. Therefore, Roferon-A should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Information from primate studies showed dose-related menstrual irregularities and an increased incidence of spontaneous abortions. Decreases in serum estradiol and progesterone concentrations have been reported in women treated with human leukocyte interferon.⁹ Therefore, fertile women should not receive Roferon-A unless they are using effective contraception during the therapy period.

The injectable solution contains benzyl alcohol. The excipient benzyl alcohol can be transmitted via the placenta. The possibility of toxicity should be taken into account in premature infants after the administration of Roferon-A solution for injection immediately prior to birth or Cesarean section.

Male fertility and teratologic evaluations have yielded no significant adverse effects to date.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Roferon-A, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Use of Roferon-A in children with Ph-positive adult-type CML is supported by evidence from adequate and well-controlled studies of Roferon-A in adults with additional data from the literature on the use of alpha interferon in children with CML. A published report on 15 children with Ph-positive adult-type CML suggests a safety profile similar to that seen in adult CML; clinical responses were also observed⁹ (see DOSAGE AND ADMINISTRATION).

For all other indications, safety and effectiveness have not been established in patients below the age of 18 years.

The injectable solutions are not indicated for use in neonates or infants and should not be used by patients in that age group. There have been rare reports of death in neonates and infants associated with excessive exposure to benzyl alcohol (see WARNINGS).

ADVERSE REACTIONS: Depressive illness and suicidal behavior, including suicidal ideation and suicides, have been reported in association with the use of alpha-interferon products. The incidence of reported depression has varied substantially among trials, possibly related to the underlying disease, dose, duration of therapy and degree of monitoring, but has been reported to be 15% or higher (see WARNINGS).

FOR PATIENTS WITH CHRONIC HEPATITIS C: The most frequent adverse experiences were reported to be possibly or probably related to therapy with 3 MIU tiw Roferon-A, were mostly mild to moderate in severity and manageable without the need for discontinuation of therapy. A relative increase in the incidence, severity and seriousness of adverse events was observed in patients receiving doses above 3 MIU tiw.

Adverse reactions associated with the 3 MIU dose include:

Flu-like Symptoms: Fatigue (58%), myalgia/arthralgia (51%), flu-like symptoms (33%), fever (28%), chills (23%), asthenia (6%), sweating (5%), leg cramps (3%) and malaise (1%).

Central and Peripheral Nervous System: Headache (52%), dizziness (13%), paresthesia (7%), confusion (7%), concentration impaired (4%) and change in taste or smell (3%).

Gastrointestinal: Nausea/vomiting (33%), diarrhea (20%), anorexia (14%), abdominal pain (12%), flatulence (3%), liver pain (3%), digestion impaired (2%) and gingival bleeding (2%).

Psychiatric: Depression (16%), irritability (15%), insomnia (14%), anxiety (5%) and behavior disturbances (3%).

Pulmonary and Cardiovascular: Dryness or inflammation of oropharynx (6%), rhinitis (4%), sinusitis (1%) and sinusitis (<1%).

Skin: Injection site reaction (29%), partial alopecia (19%), dry skin or pruritus (7%), hematoma (1%), psoriasis (<1%), cutaneous eruptions (<1%), eczema (<1%) and seborrhea (<1%).

Other: Conjunctivitis (4%), menstrual irregularity (2%) and visual acuity decreased (<1%).

Patients receiving 6 MIU tiw experienced a higher incidence of severe psychiatric events (9%) than those receiving 3 MIU tiw (6%) in two large US studies. In addition, more patients withdrew from these studies when receiving 6 MIU tiw (11%) than when receiving 3 MIU tiw (7%). Up to half of patients receiving 3 MIU or 6 MIU tiw withdrawing from the study experienced severe psychiatric events. At higher doses, depression, anxiety, and insomnia were observed more frequently. An increased incidence of fatigue, myalgia/arthralgia, headache, fever, chills, alopecia, weight loss, and dry skin or pruritus was also generally observed during treatment with higher doses of Roferon-A.

Generally there were fewer adverse events reported in the second 6 months of treatment than in the first 6 months for patients treated with 3 MIU tiw. Patients tolerant of initial therapy with Roferon-A generally tolerate re-treatment at the same dose, but tend to experience more adverse reactions at higher doses.

Infrequent adverse events (>1% but <3% incidence) included: cough, muscle cramps, diaphoresis, dyspnea, eye pain, reactivation of herpes simplex, lethargy, sexual dysfunction, stomatitis, tooth disorder, urinary tract infection, weakness in extremities.

FOR PATIENTS WITH CHRONIC MYELOGENOUS LEUKEMIA:

For patients with chronic myelogenous leukemia, the percentage of adverse events, whether related to drug therapy or not, experienced by patients treated with rIFNα-2a is given below. Severe adverse events were observed in 66% and 31% of patients on study DM84-38 and MI400, respectively. Dose reduction and temporary cessation of therapy were required frequently. Permanent cessation of Roferon-A, due to intolerable side effects, was required in 15% and 23% of patients on studies DM84-38 and MI400, respectively.

Flu-like Symptoms: Fever (92%), asthenia or fatigue (88%), myalgia (68%), chills (63%), arthralgia/bone pain (47%) and headache (44%).

Gastrointestinal: Anorexia (48%), nausea/vomiting (37%) and diarrhea (37%).

Central and Peripheral Nervous System: Headache (44%), depression (28%), decreased mental status (16%), dizziness (11%), sleep disturbances (11%), paresthesia (8%), involuntary movements (7%) and visual disturbance (6%).

Pulmonary and Cardiovascular: Coughing (19%), dyspnea (8%) and dysrhythmia (7%).

Skin: Hair changes (including alopecia) (18%), skin rash (18%), sweating (15%), dry skin (7%) and pruritus (7%).

Unknown adverse events (< 4%) reported in clinical studies included chest pain, syncope, hypotension, impotence, alterations in taste or hearing, confusion, seizures, memory loss, disturbances of libido, bruising and coagulopathy. Miscellaneous adverse events that were rarely observed included Coombs' positive hemolytic anemia, aplastic anemia, hypothyroidism, cardiomyopathy, hypertriglyceridemia and bronchospasm.

FOR PATIENTS WITH Hairy Cell Leukemia:

Constitutional (100%): Fever (92%), fatigue (86%), headache (64%), chills (64%), weight loss (33%), dizziness (21%) and flu-like symptoms (16%).

Integumentary (79%): Skin rash (44%), diaphoresis (22%), partial alopecia (17%), dry skin (17%) and pruritus (13%).

Musculoskeletal (73%): Myalgia (71%), joint or bone pain (25%) and arthritis or polyarthritis (5%).

Gastrointestinal (69%): Anorexia (43%), nausea/vomiting (39%) and diarrhea (34%).

Head and Neck (45%): Throat irritation (21%), rhinorrhea (12%) and sinusitis (11%).

Pulmonary (40%): Coughing (16%), dyspnea (12%) and pneumonia (11%).

Central Nervous System (39%): Dizziness (21%), depression (16%), sleep disturbance (10%), decreased mental status (10%), anxiety (6%), lethargy (6%), visual disturbance (6%) and confusion (5%).

Cardiovascular (39%): Chest pain (11%), edema (11%) and hypertension (11%).

Pain (34%): Pain (24%) and pain in back (16%).

Peripheral Nervous System (23%): Paresthesia (12%) and numbness (12%).

Rarely (<5%), central nervous system effects including gait disturbance, nervousness, syncope and vertigo, as well as cardiac adverse events including murmur, thrombophlebitis and hypotension were reported. Adverse experiences that occurred rarely, and may have been related to underlying disease, included ecchymosis, epistaxis, bleeding gums and petechiae. Urticaria and inflammation at the site of injection were also rarely observed.

FOR PATIENTS WITH AIDS-RELATED KAPOSI'S SARCOMA:

Flu-like Symptoms: Fatigue (95%), fever (74%), myalgia (69%), headache (66%), chills (41%) and arthralgia (24%).

Gastrointestinal: Anorexia (65%), nausea (51%), diarrhea (42%), emesis (17%) and abdominal pain (15%).

Central and Peripheral Nervous System: Dizziness (40%), decreased mental status (17%), depression (16%), paresthesia (8%), confusion (8%), diaphoresis (7%), visual disturbances (5%), sleep disturbances (5%) and numbness (3%).

Pulmonary and Cardiovascular: Coughing (27%), dyspnea (11%), edema (9%), chest pain (4%) and hypotension (4%).

Skin: Partial alopecia (22%), rash (11%) and dry skin or pruritus (5%).

Other: Weight loss (25%), change in taste (25%), dryness or inflammation of the oropharynx (14%), night sweats (8%) and rhinorrhea (4%).

Occasionally (<3%) nervous system effects including anxiety, nervousness, emotional lability, vertigo and forgetfulness, as well as cardiac adverse events, including palpitations and arrhythmia, were reported. Other adverse experiences that occurred occasionally (<3%) and may have been related to underlying disease, included sinusitis, constipation, chest congestion, pneumonia, urticaria and flatulence. Adverse experiences which occurred rarely (<1%) included ataxia, seizures, cyanosis, gastric distress, bronchospasm, pain at injection site, earache, eye irritation and rhinitis. Miscellaneous adverse experiences such as poor coordination, lethargy, muscle contractions, neuropathy, tremor, involuntary movement, syncope, aphasia, aphonia, dysarthria, amnesia, weakness and flushing of skin were observed in less than 0.5% of patients. Cases of cardiomyopathy have been observed on rare occasions in patients treated with alpha interferons.

Ex H. M

DC-456		JUL 17 2000		COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF CORRECTIONS	
X-RAY REPORT			Received		
NAME <i>CLARK, WILLIAM</i>		NUMBER <i>A45585</i>		QUARTERS <i>CA</i>	
X-RAY NUMBER		DATE OF X-RAY <i>7/13/00</i>		TECHNICIAN <i>KE</i>	
<input type="checkbox"/> TREATMENT <input checked="" type="checkbox"/> EXAMINATION		DETAILS: <i>AL GB</i> <i>US liver, spleen</i> <i>spleen size, Rbcirrhosis</i> <i>liver 15.6 x 18.0 cm dense appearing</i> <i>nl Rt kid</i> <i>spleen 11.5 x 7.9 cm</i> <i>Lt. Kid 12.4 x 7.0 cm</i> <i>study shows masses</i>			
REPORT		ABDOMINAL SONOGRAM: The liver measures 18.0 x 15.6 cm with dense texture and enlargement. No definite mass is seen with normal appearance of the hepatic veins. There are no gallstones evident. Common bile duct measures .35 cm and normal. Spleen measures 11.5 x 7.9 cm. There is no alterations involving the kidneys nor other abnormal abdominal mass seen. IMPRESSION: Liver - mildly enlarged with dense texture consistent with diffuse liver disease and/or cirrhosis. Spleen - upper normal size. No gallstones nor other significant abnormalities.			
DATE OF REPORT		Name: <i>[Signature]</i> Date: <i>7/13/00</i> Time: <i>8:15</i> A- <i>[Signature]</i> ROENTGENOLOGIST			

White—MEDICAL RECORD

Canary—X-RAY FILE

Harry K. Smith, D.O.

Pink—RADIOLOGIST FILE

REPORT

PATIENT NAME		CLARK		WILLIAM		PATIENT ID.		HY0565		SPEC.		NO.		DATE		SPEC.	
BONE		Calcium mg/dl (9.0-10.5)		9.7		Prophosphorus mg/dl (2.5-4.5)		4.2		Sodium meq/L (135-145)		142		Potassium meq/L (3.5-5.0)		3.8	
ELECTROLYTES		Chloride meq/L (94-108)		106		LDH IU/L (100-250)		142		AST (SGOT) IU/L (0-40)		56		T.BIL mg/dl (0.1-1.2)		0.4	
HEART		GGT (GPT) IU/L (0-45)		90		ALP (ALP) IU/L (0-50)		70		ALT (SGPT) IU/L (0-50)		97		Cholesterol mg/dl < 200		199	
LIPIDS		Triglycerides mg/dl (10-50)		211		HIGH		HIGH		HIGH		HIGH		MISCELLANEOUS		T. Protein g/dl (6.0-8.5)	
PROTEIN		Albumin g/dl (3.5-5.5)		4.1		A/G Ratio		1.2		BUN mg/dl (7-20)		15		Creatinine mg/dl (0.5-1.5)		1.1	
KIDNEY		T ₄ uptake %		(33-45)		Free T ₄ index		(1.5-5.0)		TSH μU/ml (0.30-5.00)		1.39		LHC Acid mg/dl (M 2.2-2.7) (F 1.5-6.7)		1.39	
THYROID		Glucose mg/dl (60-120)		77		HIGH		HIGH		EOS		0		RBC x 10 ⁶ /mm ³ (4.5-5.5)		5.10	
HEMATOLOGY		HGB g/dl (12.0-16.0)		16.2		HCT %		48.3		MCV fL (80-100)		95		MCH pg (26-34)		31.8	
		MCHC %		(31-37)		Platelets x 10 ³ /mm ³ (140-440)		33.5		WBC x 10 ³ /mm ³ (4.0-10.5)		7.0		Bands (0-5%)		3.9	
		Lymphs (20-45%)		40		Monos (0-10%)		2		Eos (0-5%)		2		BASO (0-1%)		0.0	

DR. R. RAHMAN

DIRECTOR: MARLENE DESQUITADO MD
IF YOU HAVE ANY QUESTIONS CONTACT - BRANCH: 609-988-0660 LAB: 800-223-0631
LAST PAGE OF REPORT

81-203-0234-0		TYPE S	PRIMARY LAB REPORT STATUS FINAL	Pg 2
ADDITIONAL INFORMATION SST ILV IR IRU NR				
SENT NAME LARK				
SEX WILLIAM				
AGE (YR/MOS) 3681				
DATE ENTERED 03/20/92				
DATE REPORTED 03/23/92				
TEST RESULT MICROSCOPIC FOLLOWS IF INDICATED				

CLINICAL INFORMATION		PHYSICIAN ID. SEWELL	PATIENT ID. AY5585
GRATERFORD LOCATION STATE CORRECTIONAL INSTITUTION BOX 244 GRATERFORD PA 19426- 215-489-4151 NJC			
LIMITS TEST ON FILE			

Roche Biomedical Laboratories

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